Clinical trial results:
A 24-Week Randomised, Open-Label, Study to Evaluate the Safety and Efficacy of Fesoterodine in Subjects Aged 6 To 17 Years With Symptoms of Detrusor Overactivity Associated With a Neurological Condition (Neurogenic Detrusor Overactivity)

Summary

EudraCT number	2010-022475-55
Trial protocol	SE EE FI SK GB ES GR FR NL BE RO DK DE LT
Global end of trial date	13 February 2020

Results information

Result version number	v2 (current)
This version publication date	25 April 2021
First version publication date	08 August 2020
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	A0221047

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02501928
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Pfizer Inc.
Sponsor organisation address	235 E 42nd Street, New York, United States, NY 10017
Public contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 18007181021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 18007181021, ClinicalTrials.gov_Inquiries@pfizer.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes

Notes:

Results analysis stage

Analysis stage	Final

Date of interim/final analysis	01 July 2020
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	13 February 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

1) To determine the safety and efficacy of fesoterodine 4 milligram (mg) and 8 mg following once daily treatment for 12 weeks in pediatric neurogenic detrusor overactivity (NDO) subjects with weight greater than (>) 25 kilogram (kg). 2) To determine the safety and efficacy of fesoterodine 2 mg and 4 mg following once daily treatment for 12 weeks in pediatric NDO subjects with weight less than or equal to (<=) 25 kg.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Council for Harmonization (ICH) Good Clinical Practice (GCP) guidelines. All the local regulatory requirements pertinent to safety of trial subjects were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 July 2012
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Canada: 1
Country: Number of subjects enrolled	Japan: 36
Country: Number of subjects enrolled	Korea, Republic of: 27
Country: Number of subjects enrolled	Malaysia: 9
Country: Number of subjects enrolled	Philippines: 9
Country: Number of subjects enrolled	Russian Federation: 7
Country: Number of subjects enrolled	South Africa: 3
Country: Number of subjects enrolled	Taiwan: 3
Country: Number of subjects enrolled	Turkey: 8
Country: Number of subjects enrolled	United States: 14
Country: Number of subjects enrolled	Belgium: 5
Country: Number of subjects enrolled	Estonia: 4
Country: Number of subjects enrolled	Finland: 3
Country: Number of subjects enrolled	France: 3
Country: Number of subjects enrolled	Germany: 2
Country: Number of subjects enrolled	Greece: 3
Country: Number of subjects enrolled	Italy: 12
Country: Number of subjects enrolled	Lithuania: 4
Country: Number of subjects enrolled	Poland: 3
Country: Number of subjects enrolled	Slovakia: 12
Country: Number of subjects enrolled	Spain: 9
Country: Number of subjects enrolled	Sweden: 2

Country: Number of subjects enrolled	Switzerland: 1
Country: Number of subjects enrolled	United Kingdom: 1
Worldwide total number of subjects	181
EEA total number of subjects	62

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	132
Adolescents (12-17 years)	49
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Study had 2 cohorts: cohort 1 had subjects with body weight >25 kg and cohort 2 had subjects with body weight <=25 kg. There were 2 phases in each cohort: cohort 1- active comparator phase followed by safety extension phase; cohort 2- efficacy phase followed by safety extension phase.

Period 1

Period 1 title	Active Comparator/Efficacy Phase:12Weeks
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Cohort 1: Fesoterodine 4 mg

Arm description:

Subjects with body weight >25 kg were randomised to receive fesoterodine 4 mg prolonged release (PR) tablet orally once daily for 12 weeks in active comparator phase. Active comparator phase was followed by safety extension phase, where subjects continued to receive fesoterodine 4 mg PR tablet orally once daily for another 12 weeks.

Arm type	Experimental
Investigational medicinal product name	Fesoterodine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Prolonged-release tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received fesoterodine 4 mg PR tablet orally once daily for 12 weeks in the active comparator phase.

Arm title	Cohort 1: Fesoterodine 8 mg

Arm description:

Subjects with body weight >25 kg were randomised to receive fesoterodine 4 mg PR tablet orally once daily for first 1 week and if this dose was tolerated well, subjects received fesoterodine 8 mg PR tablet orally once daily for next 11 weeks in active comparator phase. Active comparator phase was followed by safety extension phase, where subjects continued to receive fesoterodine 8 mg PR tablet orally once daily for another 12 weeks.

Arm type	Experimental
Investigational medicinal product name	Fesoterodine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Prolonged-release tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received fesoterodine 4 mg PR tablet orally once for 1 week and if this dose was tolerated well, then subjects received fesoterodine 8 mg PR tablet orally once daily for 11 weeks in the active comparator phase.

Arm title	Cohort 1: Oxybutynin

Arm description:

Subjects with body weight >25 kg were randomised to receive oxybutynin extended release (ER) tablet, at a daily dose in accordance with approved pediatric labeling and accepted practice. Dose titration was

done for first 4 weeks. After Week 4, subjects remained on the optimised daily dose for next 8 weeks, in active comparator phase.

Arm type	Active comparator
Investigational medicinal product name	Oxybutynin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Modified-release tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received oxybutynin ER tablet at a daily dose in accordance with approved pediatric labeling and accepted practice. Dose titration was done for first 4 weeks. After Week 4, subjects remained on the optimised daily dose for next 8 weeks, in active comparator phase.

Arm title	Cohort 2: Fesoterodine 2 mg

Arm description:

Subjects with body weight <=25 kg were randomised to receive fesoterodine 2 mg beads-in-capsule (BIC) capsule orally once daily for 12 weeks in efficacy phase. Active comparator phase was followed by safety extension phase, where subjects continued to receive fesoterodine 2 mg BIC capsules orally once daily for another 12 weeks.

Arm type	Experimental
Investigational medicinal product name	Fesoterodine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Subjects received fesoterodine 2 mg BIC capsule orally once daily for 12 weeks in the efficacy phase.

Arm title	Cohort 2: Fesoterodine 4 mg

Arm description:

Subjects with body weight <=25 kg were randomised to receive fesoterodine 2 mg BIC capsule orally once daily for first 1 week and if this dose was tolerated well, subjects received fesoterodine 4 mg BIC capsule orally once daily for next 11 weeks in efficacy phase. Active comparator phase was followed by safety extension phase, where subjects continued to receive fesoterodine 4 mg BIC capsule orally once daily for another 12 weeks.

Arm type	Experimental
Investigational medicinal product name	Fesoterodine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Subjects receive fesoterodine 2 mg BIC capsule orally once daily for first 1 week and if this dose was tolerated well, subjects received fesoterodine 4 mg BIC capsule orally once daily for next 11 weeks in the efficacy phase.

Number of subjects in period 1	Cohort 1: Fesoterodine 4 mg	Cohort 1: Fesoterodine 8 mg	Cohort 1: Oxybutynin
Started	42	42	40
Treated	42	42	40
Completed	33	40	36
Not completed	9	2	4
Failure to Meet Randomisation Criteria	-	1	1

Protocol deviation	2	-	1
Withdrawal By Parent/Guardian	2	-	-
Lack of efficacy	-	-	-
Medication Error Without Associated AEs	-	1	-
Unspecified	2	-	2
Adverse Events	2	-	-
Lost to follow-up	1	-	-

Number of subjects in period 1	Cohort 2: Fesoterodine 2 mg	Cohort 2: Fesoterodine 4 mg
Started	28	29
Treated	28	29
Completed	21	28
Not completed	7	1
Failure to Meet Randomisation Criteria	1	-
Protocol deviation	-	-
Withdrawal By Parent/Guardian	3	-
Lack of efficacy	1	1
Medication Error Without Associated AEs	-	-
Unspecified	-	-
Adverse Events	2	-
Lost to follow-up	-	-

Period 2

Period 2 title	Safety Extension Phase (SEP): 12 Weeks
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Cohort 1: Fesoterodine 4 mg

Arm description:

Subjects with body weight >25 kg were randomised to receive fesoterodine 4 mg PR tablet orally once daily for 12 weeks in active comparator phase. Active comparator phase was followed by safety extension phase, where subjects continued to receive fesoterodine 4 mg PR tablet orally once daily for another 12 weeks.

Arm type	Experimental
Investigational medicinal product name	Fesoterodine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Prolonged-release tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received fesoterodine 4 mg PR tablet orally once daily for 12 weeks in the safety extension phase.

Arm title	Cohort 1: Fesoterodine 8 mg

Arm description:

Subjects with body weight >25 kg were randomised to receive fesoterodine 4 mg PR tablet orally once daily for first 1 week and if this dose was tolerated well, subjects received fesoterodine 8 mg PR tablet orally once daily for next 11 weeks in active comparator phase. Active comparator phase was followed by safety extension phase, where subjects continued to receive fesoterodine 8 mg PR tablet orally once daily for another 12 weeks.

Arm type	Experimental
Investigational medicinal product name	Fesoterodine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Prolonged-release tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received fesoterodine 8 mg PR tablet orally once daily for 12 weeks in the safety extension phase.

Arm title	Cohort 1: Oxybutynin Then Fesoterodine 4 mg

Arm description:

Edit Arm Properties |Delete Subjects with body weight >25 kg who were randomised to receive oxybutynin ER tablet, at a daily dose in accordance with approved pediatric labeling and accepted practice, in active comparator phase; were allocated by investigator to receive fesoterodine 4 mg PR tablet orally once daily for 12 weeks in the safety extension phase.

Arm type	Experimental
Investigational medicinal product name	Fesoterodine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Prolonged-release tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received fesoterodine 4 mg PR tablet orally once daily for 12 weeks in the safety extension phase.

Arm title	Cohort 1: Oxybutynin Then Fesoterodine 8 mg

Arm description:

Subjects with body weight >25 kg who were randomised to receive oxybutynin ER tablet, at a daily dose in accordance with approved pediatric labeling and accepted practice, in active comparator phase; were allocated by investigator to receive fesoterodine 4 mg PR tablet orally once daily for first 1 week followed by fesoterodine 8 mg PR tablet orally once daily for another 11 weeks (if the fesoterodine 4 mg dose was well tolerated) in the safety extension phase.

Arm type	Experimental
Investigational medicinal product name	Fesoterodine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Prolonged-release tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received fesoterodine 4 mg PR tablet orally once daily for first 1 week and if dose was tolerated well, subjects received fesoterodine 8 mg PR tablet orally once daily for another 11 weeks in the safety extension phase.

Arm title	Cohort 2: Fesoterodine 2 mg

Arm description:

Subjects with body weight <=25 kg were randomised to receive fesoterodine 2 mg BIC capsule orally once daily for 12 weeks in efficacy phase. Active comparator phase was followed by safety extension phase, where subjects continued to receive fesoterodine 2 mg BIC capsules orally once daily for another 12 weeks.

Arm type	Experimental
Investigational medicinal product name	Fesoterodine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Subjects received fesoterodine 2 mg BIC capsules orally once daily for 12 weeks in the safety extension phase.

Arm title	Cohort 2: Fesoterodine 4 mg

Arm description:

Subjects with body weight <=25 kg were randomised to receive fesoterodine 2 mg BIC capsules orally once daily for first 1 week and if this dose was tolerated well, subjects received fesoterodine 4 mg BIC capsules orally once daily for next 11 weeks in efficacy phase. Active comparator phase was followed by safety extension phase, where subjects continued to receive fesoterodine 4 mg BIC capsules orally once daily for another 12 weeks.

Arm type	Experimental
Investigational medicinal product name	Fesoterodine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Subjects received fesoterodine 4 mg BIC capsules orally once daily for 12 weeks in the safety extension phase.

Number of subjects in period 2	Cohort 1: Fesoterodine 4 mg	Cohort 1: Fesoterodine 8 mg	Cohort 1: Oxybutynin Then Fesoterodine 4 mg
Started	33	40	16
Treated	30	37	16
Completed	30	36	15
Not completed	3	4	1
Lack of efficacy	1	2	-
SEP: Withdrawal By Parent/Guardian	1	1	-
SEP: Medication Error No Associated AEs	-	-	1
SEP: Adverse Event	1	1	-

Number of subjects in period 2	Cohort 1: Oxybutynin Then Fesoterodine 8 mg	Cohort 2: Fesoterodine 2 mg	Cohort 2: Fesoterodine 4 mg
Started	20	21	28
Treated	20	20	28
Completed	20	20	28
Not completed	0	1	0

Lack of efficacy	-	-	-
SEP: Withdrawal By Parent/Guardian	-	-	-
SEP: Medication Error No Associated AEs	-	-	-
SEP: Adverse Event	-	1	-

Baseline characteristics

Reporting groups	
Reporting group title	Cohort 1: Fesoterodine 4 mg
Reporting group description:	
Subjects with body weight >25 kg were randomised to receive fesoterodine 4 mg prolonged release (PR) tablet orally once daily for 12 weeks in active comparator phase. Active comparator phase was followed by safety extension phase, where subjects continued to receive fesoterodine 4 mg PR tablet orally once daily for another 12 weeks.	
Reporting group title	Cohort 1: Fesoterodine 8 mg
Reporting group description:	
Subjects with body weight >25 kg were randomised to receive fesoterodine 4 mg PR tablet orally once daily for first 1 week and if this dose was tolerated well, subjects received fesoterodine 8 mg PR tablet orally once daily for next 11 weeks in active comparator phase. Active comparator phase was followed by safety extension phase, where subjects continued to receive fesoterodine 8 mg PR tablet orally once daily for another 12 weeks.	
Reporting group title	Cohort 1: Oxybutynin
Reporting group description:	
Subjects with body weight >25 kg were randomised to receive oxybutynin extended release (ER) tablet, at a daily dose in accordance with approved pediatric labeling and accepted practice. Dose titration was done for first 4 weeks. After Week 4, subjects remained on the optimised daily dose for next 8 weeks, in active comparator phase.	
Reporting group title	Cohort 2: Fesoterodine 2 mg
Reporting group description:	
Subjects with body weight <=25 kg were randomised to receive fesoterodine 2 mg beads-in-capsule (BIC) capsule orally once daily for 12 weeks in efficacy phase. Active comparator phase was followed by safety extension phase, where subjects continued to receive fesoterodine 2 mg BIC capsules orally once daily for another 12 weeks.	
Reporting group title	Cohort 2: Fesoterodine 4 mg
Reporting group description:	
Subjects with body weight <=25 kg were randomised to receive fesoterodine 2 mg BIC capsule orally once daily for first 1 week and if this dose was tolerated well, subjects received fesoterodine 4 mg BIC capsule orally once daily for next 11 weeks in efficacy phase. Active comparator phase was followed by safety extension phase, where subjects continued to receive fesoterodine 4 mg BIC capsule orally once daily for another 12 weeks.	

Reporting group values	Cohort 1: Fesoterodine 4 mg	Cohort 1: Fesoterodine 8 mg	Cohort 1: Oxybutynin
Number of subjects	42	42	40
Age Categorical Units: Subject			
<=18 years	42	42	40
Between 18 and 65 years	0	0	0
>=65 years	0	0	0
Sex: Female, Male Units: Subject			
Female	16	22	17
Male	26	20	23
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	14	18	22
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	2	0	1

White	24	24	17
More than one race	0	0	0
Unknown or Not Reported	2	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	3	2	1
Not Hispanic or Latino	39	40	39
Unknown or Not Reported	0	0	0

Reporting group values	Cohort 2: Fesoterodine 2 mg	Cohort 2: Fesoterodine 4 mg	Total
Number of subjects	28	29	181
Age Categorical Units: Subject			
<=18 years	28	29	181
Between 18 and 65 years	0	0	0
>=65 years	0	0	0
Sex: Female, Male Units: Subject			
Female	12	19	86
Male	16	10	95
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	16	16	86
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	3
White	12	11	88
More than one race	0	0	0
Unknown or Not Reported	0	2	4
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	2	8
Not Hispanic or Latino	28	27	173
Unknown or Not Reported	0	0	0

End points

End points reporting groups

Reporting group title	Cohort 1: Fesoterodine 4 mg

Reporting group description:

Subjects with body weight >25 kg were randomised to receive fesoterodine 4 mg prolonged release (PR) tablet orally once daily for 12 weeks in active comparator phase. Active comparator phase was followed by safety extension phase, where subjects continued to receive fesoterodine 4 mg PR tablet orally once daily for another 12 weeks.

Reporting group title	Cohort 1: Fesoterodine 8 mg

Reporting group description:

Subjects with body weight >25 kg were randomised to receive fesoterodine 4 mg PR tablet orally once daily for first 1 week and if this dose was tolerated well, subjects received fesoterodine 8 mg PR tablet orally once daily for next 11 weeks in active comparator phase. Active comparator phase was followed by safety extension phase, where subjects continued to receive fesoterodine 8 mg PR tablet orally once daily for another 12 weeks.

Reporting group title	Cohort 1: Oxybutynin

Reporting group description:

Subjects with body weight >25 kg were randomised to receive oxybutynin extended release (ER) tablet, at a daily dose in accordance with approved pediatric labeling and accepted practice. Dose titration was done for first 4 weeks. After Week 4, subjects remained on the optimised daily dose for next 8 weeks, in active comparator phase.

Reporting group title	Cohort 2: Fesoterodine 2 mg

Reporting group description:

Subjects with body weight <=25 kg were randomised to receive fesoterodine 2 mg beads-in-capsule (BIC) capsule orally once daily for 12 weeks in efficacy phase. Active comparator phase was followed by safety extension phase, where subjects continued to receive fesoterodine 2 mg BIC capsules orally once daily for another 12 weeks.

Reporting group title	Cohort 2: Fesoterodine 4 mg

Reporting group description:

Subjects with body weight <=25 kg were randomised to receive fesoterodine 2 mg BIC capsule orally once daily for first 1 week and if this dose was tolerated well, subjects received fesoterodine 4 mg BIC capsule orally once daily for next 11 weeks in efficacy phase. Active comparator phase was followed by safety extension phase, where subjects continued to receive fesoterodine 4 mg BIC capsule orally once daily for another 12 weeks.

Reporting group title	Cohort 1: Fesoterodine 4 mg

Reporting group description:

Subjects with body weight >25 kg were randomised to receive fesoterodine 4 mg PR tablet orally once daily for 12 weeks in active comparator phase. Active comparator phase was followed by safety extension phase, where subjects continued to receive fesoterodine 4 mg PR tablet orally once daily for another 12 weeks.

Reporting group title	Cohort 1: Fesoterodine 8 mg

Reporting group description:

Subjects with body weight >25 kg were randomised to receive fesoterodine 4 mg PR tablet orally once daily for first 1 week and if this dose was tolerated well, subjects received fesoterodine 8 mg PR tablet orally once daily for next 11 weeks in active comparator phase. Active comparator phase was followed by safety extension phase, where subjects continued to receive fesoterodine 8 mg PR tablet orally once daily for another 12 weeks.

Reporting group title	Cohort 1: Oxybutynin Then Fesoterodine 4 mg

Reporting group description:

Edit Arm Properties |Delete Subjects with body weight >25 kg who were randomised to receive oxybutynin ER tablet, at a daily dose in accordance with approved pediatric labeling and accepted practice, in active comparator phase; were allocated by investigator to receive fesoterodine 4 mg PR tablet orally once daily for 12 weeks in the safety extension phase.

Reporting group title	Cohort 1: Oxybutynin Then Fesoterodine 8 mg

Reporting group description:

Subjects with body weight >25 kg who were randomised to receive oxybutynin ER tablet, at a daily dose in accordance with approved pediatric labeling and accepted practice, in active comparator phase; were allocated by investigator to receive fesoterodine 4 mg PR tablet orally once daily for first 1 week

followed by fesoterodine 8 mg PR tablet orally once daily for another 11 weeks (if the fesoterodine 4 mg dose was well tolerated) in the safety extension phase.

Reporting group title	Cohort 2: Fesoterodine 2 mg

Reporting group description:

Subjects with body weight <=25 kg were randomised to receive fesoterodine 2 mg BIC capsule orally once daily for 12 weeks in efficacy phase. Active comparator phase was followed by safety extension phase, where subjects continued to receive fesoterodine 2 mg BIC capsules orally once daily for another 12 weeks.

Reporting group title	Cohort 2: Fesoterodine 4 mg

Reporting group description:

Subjects with body weight <=25 kg were randomised to receive fesoterodine 2 mg BIC capsules orally once daily for first 1 week and if this dose was tolerated well, subjects received fesoterodine 4 mg BIC capsules orally once daily for next 11 weeks in efficacy phase. Active comparator phase was followed by safety extension phase, where subjects continued to receive fesoterodine 4 mg BIC capsules orally once daily for another 12 weeks.

Subject analysis set title	Cohort 1, Active Comparator Phase: Fesoterodine 4 mg
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with body weight >25 kg were randomised to receive fesoterodine 4 mg PR tablet orally once daily for 12 weeks in active comparator phase. Full analysis set included all subjects who have been randomised, received at least one dose of study medication and have provided baseline primary endpoint data.

Subject analysis set title	Cohort 1, Active Comparator Phase: Fesoterodine 8 mg
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with body weight >25 kg were randomised to receive fesoterodine 4 mg PR tablets orally once daily for first 1 week and if dose was tolerated well, then subjects received 8 mg PR tablet orally once daily for next 11 weeks in active comparator phase. Full analysis set included all subjects who have been randomised, received at least one dose of study medication and have provided baseline primary endpoint data.

Subject analysis set title	Cohort 1, Active Comparator Phase: Oxybutynin
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with body weight >25 kg were randomised to receive oxybutynin ER tablet, at a daily dose in accordance with approved pediatric labeling and accepted practice. Dose titration was done for first 4 weeks. After Week 4, subjects remained on the optimised daily dose for next 8 weeks, in active comparator phase. Full analysis set included all subjects who have been randomised, received at least one dose of study medication and have provided baseline primary endpoint data.

Subject analysis set title	Cohort 2, Efficacy Phase: Fesoterodine 2 mg
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with body weight <=25 kg were randomised to receive fesoterodine 2 mg BIC capsule orally once daily for 12 weeks in efficacy phase. Full analysis set included all subjects who have been randomised, received at least one dose of study medication and have provided baseline primary endpoint data.

Subject analysis set title	Cohort 2, Efficacy Phase: Fesoterodine 4 mg
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with body weight <=25 kg were randomised to receive fesoterodine 2 mg BIC capsule orally once daily for first 1 week and if dose was tolerated well, then subjects received 4 mg BIC capsule orally once daily for next 11 weeks in efficacy phase. Full analysis set included all subjects who have been randomised, received at least one dose of study medication and have provided baseline primary endpoint data.

Subject analysis set title	Cohort 1, Active Comparator Phase: Fesoterodine 4 mg
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with body weight >25 kg were randomised to receive fesoterodine 4 mg PR tablet orally once daily for 12 weeks in active comparator phase. Safety analysis set included all subjects who received at least one dose of study medication during the relevant phase.

Subject analysis set title	Cohort 1, Active Comparator Phase: Fesoterodine 8 mg

Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with body weight >25 kg were randomised to receive fesoterodine 4 mg PR tablets orally once daily for first 1 week and if dose was tolerated well, then subjects received 8 mg PR tablet orally once daily for next 11 weeks in active comparator phase. Safety analysis set included all subjects who received at least one dose of study medication during the relevant phase.

Subject analysis set title	Cohort 1, Active Comparator Phase: Oxybutynin
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with body weight >25 kg were randomised to receive oxybutynin ER tablet, at a daily dose in accordance with approved pediatric labeling and accepted practice. Dose titration was done for first 4 weeks. After Week 4, subjects remained on the optimised daily dose for next 8 weeks, in active comparator phase. Safety analysis set included all subjects who received at least one dose of study medication during the relevant phase.

Subject analysis set title	Cohort 2, Efficacy Phase: Fesoterodine 2 mg
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with body weight <=25 kg were randomised to receive fesoterodine 2 mg BIC capsule orally once daily for 12 weeks in efficacy phase. Safety analysis set included all subjects who received at least one dose of study medication during the relevant phase.

Subject analysis set title	Cohort 2, Efficacy Phase: Fesoterodine 4 mg
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with body weight <=25 kg were randomised to receive fesoterodine 2 mg BIC capsule orally once daily for first 1 week and if dose was tolerated well, then subjects received 4 mg BIC capsule orally once daily for next 11 weeks in efficacy phase. Safety analysis set included all subjects who received at least one dose of study medication during the relevant phase.

Subject analysis set title	Cohort 1, Safety Extension Phase: Fesoterodine 4 mg
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with body weight >25 kg received fesoterodine 4 mg PR tablet orally once daily for 12 weeks in safety extension phase. Safety analysis set included all subjects who received at least one dose of study medication during the relevant phase.

Subject analysis set title	Cohort 1, Safety Extension Phase (SEP): Fesoterodine 8 mg
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with body weight >25 kg received fesoterodine 8 mg PR tablet orally once daily for 12 weeks in safety extension phase. Safety analysis set included all subjects who received at least one dose of study medication during the relevant phase.

Subject analysis set title	Cohort 1, SEP: Oxybutynin Then Fesoterodine 4 mg
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with body weight >25 kg who were randomised to receive oxybutynin ER tablet, at a daily dose in accordance with approved pediatric labeling and accepted practice, in active comparator phase; were allocated by investigator to receive fesoterodine 4 mg PR tablet orally once daily for 12 weeks in the safety extension phase. Safety analysis set included all subjects who received at least one dose of study medication during the relevant phase.

Subject analysis set title	Cohort 1, SEP: Oxybutynin Then Fesoterodine 8 mg
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with body weight >25 kg who were randomised to receive oxybutynin ER tablet, at a daily dose in accordance with approved pediatric labeling and accepted practice, in active comparator phase; were allocated by investigator to receive fesoterodine 4 mg PR tablet orally once daily for first 1 week followed by fesoterodine 8 mg PR tablet orally once daily for another 11 weeks (if the fesoterodine 4 mg dose was well tolerated) in the safety extension phase. Safety analysis set included all subjects who received at least one dose of study medication during the relevant phase.

Subject analysis set title	Cohort 2, Safety Extension Phase: Fesoterodine 2 mg
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with body weight <=25 kg received fesoterodine 2 mg BIC capsules orally once daily for 12 weeks in safety extension phase. Safety analysis set included all subjects who received at least one dose of study medication during the relevant phase.

Subject analysis set title	Cohort 2, Safety Extension Phase: Fesoterodine 4 mg
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with body weight <=25 kg received fesoterodine 4 mg BIC capsules orally once daily for 12 weeks in safety extension phase. Safety analysis set included all subjects who received at least one dose of study medication during the relevant phase. Safety analysis set included all subjects who received at least one dose of study medication during the relevant phase.

Subject analysis set title	Cohort 1, Safety Extension Phase: Fesoterodine 8 mg
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with body weight >25 kg received fesoterodine 8 mg PR tablet orally once daily for 12 weeks in safety extension phase. Safety analysis set included all subjects who received at least one dose of study medication during the relevant phase.

Subject analysis set title	Fesoterodine Pooled
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects received any dose of fesoterodine in the study from Week 1 to Week 24 and provided at least 1 PK observation.

Primary: Change From Baseline in Maximum Cystometric Bladder Capacity at Week 12: Active Comparator Phase (ACP)/Efficacy Phase (EP)

End point title	Change From Baseline in Maximum Cystometric Bladder Capacity at Week 12: Active Comparator Phase (ACP)/Efficacy Phase (EP)

End point description:

Maximum cystometric bladder capacity was defined as maximal tolerable cystometric capacity, until voiding or leaking begins or at a pressure of >=40 centimeter (cm) water (H2O). Full analysis set included all subjects who were randomised in the study and received at least 1 dose of study medication and had provided baseline primary endpoint data.

End point type	Primary

End point timeframe:

Baseline, Week 12

End point values	Cohort 1, Active Comparator Phase: Fesoterodine 4 mg	Cohort 1, Active Comparator Phase: Fesoterodine 8 mg	Cohort 1, Active Comparator Phase: Oxybutynin	Cohort 2, Efficacy Phase: Fesoterodine 2 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	41	41	38	25
Units: milliliter				
least squares mean (confidence interval 95%)	58.12 (28.84 to 87.39)	83.36 (54.22 to 112.49)	87.17 (56.82 to 117.53)	23.49 (3.03 to 43.95)

End point values	Cohort 2, Efficacy Phase: Fesoterodine 4 mg			
Subject group type	Subject analysis set			

Number of subjects analysed	28			
Units: milliliter				
least squares mean (confidence interval 95%)	40.17 (20.84 to 59.50)			

Attachments (see zip file)	Statistical Analysis for Change From Baseline/Endpoint 1

Statistical analyses

Statistical analysis title	Cohort 1, ACP: Fesoterodine 4 mg vs Oxybutynin
Comparison groups	Cohort 1, Active Comparator Phase: Fesoterodine 4 mg v Cohort 1, Active Comparator Phase: Oxybutynin
Number of subjects included in analysis	79
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Least square (LS) Mean
Point estimate	-29.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-71.42
upper limit	13.31

Statistical analysis title	Cohort 1, ACP: Fesoterodine 8 mg vs Oxybutynin
Comparison groups	Cohort 1, Active Comparator Phase: Fesoterodine 8 mg v Cohort 1, Active Comparator Phase: Oxybutynin
Number of subjects included in analysis	79
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in LS Mean
Point estimate	-3.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	-45.87
upper limit	38.23

Secondary: Change From Baseline in Detrusor Pressure at Maximum Bladder Capacity at Week 12: Active Comparator Phase (ACP)/Efficacy Phase (EP)

End point title	Change From Baseline in Detrusor Pressure at Maximum Bladder Capacity at Week 12: Active Comparator Phase (ACP)/Efficacy Phase (EP)

End point description:

Detrusor pressure at maximum urinary bladder capacity was measured using urodynamic testing. Full analysis set included all subjects who were randomised in the study and received at least 1 dose of study medication and had provided baseline primary endpoint data. Here 'Number of Subjects Analysed'

signifies subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Cohort 1, Active Comparator Phase: Fesoterodine 4 mg	Cohort 1, Active Comparator Phase: Fesoterodine 8 mg	Cohort 1, Active Comparator Phase: Oxybutynin	Cohort 2, Efficacy Phase: Fesoterodine 2 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	40	41	38	25
Units: cm H2O				
least squares mean (confidence interval 95%)	-2.86 (-7.60 to 1.87)	-1.57 (-6.25 to 3.12)	-2.39 (-7.27 to 2.48)	-2.74 (-10.62 to 5.15)

End point values	Cohort 2, Efficacy Phase: Fesoterodine 4 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	28			
Units: cm H2O				
least squares mean (confidence interval 95%)	-9.73 (-17.18 to -2.28)			

Attachments (see zip file)	Statistical Analysis for Change From Baseline/Endpoint 2

Statistical analyses

Statistical analysis title	Cohort 1, ACP: Fesoterodine 4 mg vs Oxybutynin
Comparison groups	Cohort 1, Active Comparator Phase: Fesoterodine 4 mg v Cohort 1, Active Comparator Phase: Oxybutynin
Number of subjects included in analysis	78
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in LS Mean
Point estimate	-0.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.28
upper limit	6.33

Statistical analysis title	Cohort 1, ACP: Fesoterodine 8 mg vs Oxybutynin
Comparison groups	Cohort 1, Active Comparator Phase: Fesoterodine 8 mg v Cohort 1, Active Comparator Phase: Oxybutynin
Number of subjects included in analysis	79
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in LS Mean
Point estimate	0.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.96
upper limit	7.6

Secondary: Number of Subjects With Shift From Baseline at Week 12 in Involuntary Detrusor Contractions (IDC): Active Comparator Phase (ACP)/Efficacy Phase (EP)

End point title	Number of Subjects With Shift From Baseline at Week 12 in Involuntary Detrusor Contractions (IDC): Active Comparator Phase (ACP)/Efficacy Phase (EP)

End point description:

In this end point, shift data have been reported using 4 categories: (1) number of subjects who did not have IDC at Baseline and at Week 12, (2) number of subjects who did not have IDC at Baseline but had IDC at Week 12, (3) number of subjects who had IDC at Baseline but no IDC at Week 12, and (4) number of subjects who had IDC at Baseline and at Week 12. Full analysis set included all subjects who were randomised in the study and received at least 1 dose of study medication and had provided baseline primary endpoint data.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Cohort 1, Active Comparator Phase: Fesoterodine 4 mg	Cohort 1, Active Comparator Phase: Fesoterodine 8 mg	Cohort 1, Active Comparator Phase: Oxybutynin	Cohort 2, Efficacy Phase: Fesoterodine 2 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	41	41	38	25
Units: subjects				
Baseline IDC = No; Week 12 IDC = No	12	4	6	0
Baseline IDC = No; Week 12 IDC = Yes	2	1	0	0
Baseline IDC = Yes; Week 12 IDC = No	9	18	14	6
Baseline IDC = Yes; Week 12 IDC = Yes	18	18	18	19

End point values	Cohort 2, Efficacy Phase: Fesoterodine 4 mg			

Subject group type	Subject analysis set			
Number of subjects analysed	28			
Units: subjects				
Baseline IDC = No; Week 12 IDC = No	1			
Baseline IDC = No; Week 12 IDC = Yes	0			
Baseline IDC = Yes; Week 12 IDC = No	11			
Baseline IDC = Yes; Week 12 IDC = Yes	16			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Bladder Volume at First Involuntary Detrusor Contraction (IDC) at Week 12: Active Comparator Phase (ACP)/Efficacy Phase (EP)

End point title	Change From Baseline in Bladder Volume at First Involuntary Detrusor Contraction (IDC) at Week 12: Active Comparator Phase (ACP)/Efficacy Phase (EP)

End point description:

Bladder volume at first IDC was measured using urodynamic testing. Full analysis set included all subjects who were randomised in the study and received at least 1 dose of study medication and had provided baseline primary endpoint data. Here 'Number of Subjects Analysed' signifies subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Cohort 1, Active Comparator Phase: Fesoterodine 4 mg	Cohort 1, Active Comparator Phase: Fesoterodine 8 mg	Cohort 1, Active Comparator Phase: Oxybutynin	Cohort 2, Efficacy Phase: Fesoterodine 2 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	26	36	32	25
Units: milliliter				
least squares mean (confidence interval 95%)	30.53 (2.42 to 58.64)	26.06 (2.19 to 49.92)	41.31 (15.92 to 66.70)	23.80 (-1.60 to 49.19)

End point values	Cohort 2, Efficacy Phase: Fesoterodine 4 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	27			
Units: milliliter				
least squares mean (confidence interval 95%)	31.26 (6.85 to 55.68)			

Attachments (see zip file)	Statistical Analysis for Change From Baseline/Endpoint 4

Statistical analyses

Statistical analysis title	Cohort 1, ACP: Fesoterodine 4 mg vs Oxybutynin
Comparison groups	Cohort 1, Active Comparator Phase: Fesoterodine 4 mg v Cohort 1, Active Comparator Phase: Oxybutynin
Number of subjects included in analysis	58
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in LS Mean
Point estimate	-10.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	-48.75
upper limit	27.19

Statistical analysis title	Cohort 1, ACP: Fesoterodine 8 mg vs Oxybutynin
Comparison groups	Cohort 1, Active Comparator Phase: Fesoterodine 8 mg v Cohort 1, Active Comparator Phase: Oxybutynin
Number of subjects included in analysis	68
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in LS Mean
Point estimate	-15.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	-50.15
upper limit	19.64

Secondary: Change From Baseline in Bladder Compliance at Week 12: Active Comparator Phase (ACP)/Efficacy Phase (EP)

End point title	Change From Baseline in Bladder Compliance at Week 12: Active Comparator Phase (ACP)/Efficacy Phase (EP)

End point description:

Bladder compliance was defined as change in bladder volume in milliliter (mL) divided by change in bladder pressure in cm H2O (during the same time when change in bladder volume was estimated). Full analysis set included all subjects who were randomised in the study and received at least 1 dose of study medication and had provided baseline primary endpoint data. Here 'Number of Subjects Analysed' signifies subjects evaluable for this endpoint.

End point type	Secondary
End point timeframe:	
Baseline, Week 12	

End point values	Cohort 1, Active Comparator Phase: Fesoterodine 4 mg	Cohort 1, Active Comparator Phase: Fesoterodine 8 mg	Cohort 1, Active Comparator Phase: Oxybutynin	Cohort 2, Efficacy Phase: Fesoterodine 2 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	40	40	38	25
Units: mL per cm H2O				
least squares mean (confidence interval 95%)	6.40 (-0.48 to 13.28)	5.41 (-1.49 to 12.32)	11.36 (4.30 to 18.42)	12.44 (-0.64 to 25.53)

End point values	Cohort 2, Efficacy Phase: Fesoterodine 4 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	28			
Units: mL per cm H2O				
least squares mean (confidence interval 95%)	16.44 (4.08 to 28.80)			

Attachments (see zip file)	Statistical Analysis for Change From Baseline/Endpoint 5

Statistical analyses

Statistical analysis title	Cohort 1, ACP: Fesoterodine 4 mg vs Oxybutynin
Comparison groups	Cohort 1, Active Comparator Phase: Fesoterodine 4 mg v Cohort 1, Active Comparator Phase: Oxybutynin
Number of subjects included in analysis	78
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in LS Mean
Point estimate	-4.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.81
upper limit	4.89

Statistical analysis title	Cohort 1, ACP: Fesoterodine 8 mg vs Oxybutynin
Comparison groups	Cohort 1, Active Comparator Phase: Fesoterodine 8 mg v Cohort 1, Active Comparator Phase: Oxybutynin
Number of subjects included in analysis	78
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in LS Mean
Point estimate	-5.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.85
upper limit	3.95

Secondary: Change From Baseline in Mean Number of Micturitions per 24 Hours at Week 12: Active Comparator Phase (ACP)/Efficacy Phase (EP)

End point title	Change From Baseline in Mean Number of Micturitions per 24 Hours at Week 12: Active Comparator Phase (ACP)/Efficacy Phase (EP)

End point description:

The mean number of micturitions per 24 hours were calculated as the total number of micturitions divided by the total number of diary days collected at the assessment time point. Number of diary days collected at the assessment time point = number of calendar days when the diary was completed on, even if it was not a full 24 hour period. This endpoint was only calculated for subjects with >0 micturitions at Baseline. Full analysis set included all subjects who were randomised in the study and received at least 1 dose of study medication and had provided baseline primary endpoint data. Here 'Number of Subjects Analysed' signifies subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Cohort 1, Active Comparator Phase: Fesoterodine 4 mg	Cohort 1, Active Comparator Phase: Fesoterodine 8 mg	Cohort 1, Active Comparator Phase: Oxybutynin	Cohort 2, Efficacy Phase: Fesoterodine 2 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	18	21	26	14
Units: micturitions per 24 hours				
least squares mean (confidence interval 95%)	-1.07 (-1.88 to -0.25)	-0.68 (-1.44 to 0.08)	-0.97 (-1.65 to -0.29)	-0.37 (-1.10 to 0.36)

End point values	Cohort 2, Efficacy Phase: Fesoterodine 4 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	17			

Units: micturitions per 24 hours				
least squares mean (confidence interval 95%)	-0.70 (-1.36 to -0.04)			

Attachments (see zip file)	Statistical Analysis for Change From Baseline/Endpoint 6

Statistical analyses

Statistical analysis title	Cohort 1, ACP: Fesoterodine 4 mg vs Oxybutynin
Comparison groups	Cohort 1, Active Comparator Phase: Fesoterodine 4 mg v Cohort 1, Active Comparator Phase: Oxybutynin
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in LS Mean
Point estimate	-0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.16
upper limit	0.97

Statistical analysis title	Cohort 1, ACP: Fesoterodine 8 mg vs Oxybutynin
Comparison groups	Cohort 1, Active Comparator Phase: Fesoterodine 8 mg v Cohort 1, Active Comparator Phase: Oxybutynin
Number of subjects included in analysis	47
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in LS Mean
Point estimate	0.28
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.74
upper limit	1.31

Secondary: Change From Baseline in Mean Number of Catheterisations per 24 Hours at Week 12: Active Comparator Phase (ACP)/Efficacy Phase (EP)

End point title	Change From Baseline in Mean Number of Catheterisations per 24 Hours at Week 12: Active Comparator Phase (ACP)/Efficacy Phase (EP)

End point description:

The mean number of catheterisations per 24 hours were calculated as the total number of catheterisations divided by the total number of diary days collected at the assessment time point. Number of diary days collected at the assessment time point = number of calendar days when the diary was completed on; even if it was not a full 24 hour period. This endpoint was only calculated for

subjects with >0 catheterisations at Baseline. Full analysis set included all subjects who were randomised in the study and received at least 1 dose of study medication and had provided baseline primary endpoint data. Here 'Number of Subjects Analysed' signifies subjects evaluable for this endpoint.

End point type	Secondary
End point timeframe:	
Baseline, Week 12	

End point values	Cohort 1, Active Comparator Phase: Fesoterodine 4 mg	Cohort 1, Active Comparator Phase: Fesoterodine 8 mg	Cohort 1, Active Comparator Phase: Oxybutynin	Cohort 2, Efficacy Phase: Fesoterodine 2 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	37	33	31	22
Units: catheterisations per 24 hours				
least squares mean (confidence interval 95%)	-0.30 (-0.63 to 0.04)	-0.32 (-0.68 to 0.03)	-0.34 (-0.71 to 0.02)	-0.10 (-0.50 to 0.29)

End point values	Cohort 2, Efficacy Phase: Fesoterodine 4 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	24			
Units: catheterisations per 24 hours				
least squares mean (confidence interval 95%)	-0.22 (-0.60 to 0.16)			

Attachments (see zip file)	Statistical Analysis for Change From Baseline/Endpoint 7

Statistical analyses

Statistical analysis title	Cohort 1, ACP: Fesoterodine 4 mg vs Oxybutynin
Comparison groups	Cohort 1, Active Comparator Phase: Fesoterodine 4 mg v Cohort 1, Active Comparator Phase: Oxybutynin
Number of subjects included in analysis	68
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in LS Mean
Point estimate	0.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.45
upper limit	0.54

Statistical analysis title	Cohort 1, ACP: Fesoterodine 8 mg vs Oxybutynin
Comparison groups	Cohort 1, Active Comparator Phase: Fesoterodine 8 mg v Cohort 1, Active Comparator Phase: Oxybutynin
Number of subjects included in analysis	64
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in LS Mean
Point estimate	0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.49
upper limit	0.52

Secondary: Change From Baseline in Mean Number of Micturitions or Catheterisations per 24 Hours at Week 12: Active Comparator Phase (ACP)/Efficacy Phase (EP)

End point title	Change From Baseline in Mean Number of Micturitions or Catheterisations per 24 Hours at Week 12: Active Comparator Phase (ACP)/Efficacy Phase (EP)

End point description:

The mean number of micturitions or catheterisations combined per 24 hours were calculated as the total number of micturitions and catheterisations combined divided by the total number of diary days collected at the assessment point. Number of diary days collected at the assessment time point = number of calendar days when the diary was completed; even if it was not a full 24 hour (hrs) period. This enpoint was evaluated in those subjects who had micturitions or catheterisations >0 at Baseline. Full analysis set included all subjects who were randomised in the study and received at least 1 dose of study medication and had provided baseline primary endpoint data. Here 'Number of Subjects Analysed' signifies subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Cohort 1, Active Comparator Phase: Fesoterodine 4 mg	Cohort 1, Active Comparator Phase: Fesoterodine 8 mg	Cohort 1, Active Comparator Phase: Oxybutynin	Cohort 2, Efficacy Phase: Fesoterodine 2 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	41	37	38	23
Units: micturitions and catheterisations/24 hrs				
least squares mean (confidence interval 95%)	-0.61 (-1.08 to -0.14)	-0.60 (-1.09 to -0.11)	-0.75 (-1.24 to -0.26)	-0.24 (-0.67 to 0.19)

End point values	Cohort 2, Efficacy Phase: Fesoterodine 4 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	26			
Units: micturitions and catheterisations/24 hrs				
least squares mean (confidence interval 95%)	-0.28 (-0.68 to 0.12)			

Attachments (see zip file)	Statistical Analysis for Change From Baseline/Endpoint 8

Statistical analyses

Statistical analysis title	Cohort 1, ACP: Fesoterodine 8 mg vs Oxybutynin
Comparison groups	Cohort 1, Active Comparator Phase: Fesoterodine 8 mg v Cohort 1, Active Comparator Phase: Oxybutynin
Number of subjects included in analysis	75
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in LS Mean
Point estimate	0.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.54
upper limit	0.84

Statistical analysis title	Cohort 1, ACP: Fesoterodine 4 mg vs Oxybutynin
Comparison groups	Cohort 1, Active Comparator Phase: Fesoterodine 4 mg v Cohort 1, Active Comparator Phase: Oxybutynin
Number of subjects included in analysis	79
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in LS Mean
Point estimate	0.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.53
upper limit	0.82

Secondary: Change From Baseline in Mean Number of Incontinence Episodes per 24 Hours at Week 12: Active Comparator Phase (ACP)/Efficacy Phase (EP)

End point title	Change From Baseline in Mean Number of Incontinence

	Episodes per 24 Hours at Week 12: Active Comparator Phase (ACP)/Efficacy Phase (EP)

End point description:

The mean number of incontinence episodes per 24 hours were calculated as the total number of incontinence episodes divided by the total number of diary days collected at the assessment time point. Number of diary days collected at the assessment time point = number of calendar days when the diary was completed; even if it was not a full 24 hour period. This endpoint was only calculated for subjects with >0 incontinence episodes at Baseline. Full analysis set included all subjects who were randomised in the study and received at least 1 dose of study medication and had provided baseline primary endpoint data. Here 'Number of subjects Analysed' signifies subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Cohort 1, Active Comparator Phase: Fesoterodine 4 mg	Cohort 1, Active Comparator Phase: Fesoterodine 8 mg	Cohort 1, Active Comparator Phase: Oxybutynin	Cohort 2, Efficacy Phase: Fesoterodine 2 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	33	33	35	22
Units: incontinence episodes per 24 hours				
least squares mean (confidence interval 95%)	-0.46 (-0.92 to -0.00)	-0.89 (-1.35 to -0.43)	-1.01 (-1.46 to -0.56)	-0.38 (-0.95 to 0.20)

End point values	Cohort 2, Efficacy Phase: Fesoterodine 4 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	20			
Units: incontinence episodes per 24 hours				
least squares mean (confidence interval 95%)	-0.69 (-1.29 to -0.08)			

Attachments (see zip file)	Statistical Analysis for Change From Baseline/Endpoint 9

Statistical analyses

Statistical analysis title	Cohort 1, ACP: Fesoterodine 4 mg vs Oxybutynin
Comparison groups	Cohort 1, Active Comparator Phase: Fesoterodine 4 mg v Cohort 1, Active Comparator Phase: Oxybutynin
Number of subjects included in analysis	68
Analysis specification	Pre-specified
Analysis type	other

Parameter estimate	Difference in LS Mean
Point estimate	0.55
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.09
upper limit	1.19

Statistical analysis title	Cohort 1, ACP: Fesoterodine 8 mg vs Oxybutynin
Comparison groups	Cohort 1, Active Comparator Phase: Fesoterodine 8 mg v Cohort 1, Active Comparator Phase: Oxybutynin
Number of subjects included in analysis	68
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in LS Mean
Point estimate	0.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.52
upper limit	0.77

Secondary: Change From Baseline in Mean Number of Urgency Episodes per 24 Hours at Week 12: Active Comparator Phase (ACP)/Efficacy Phase (EP)

End point title	Change From Baseline in Mean Number of Urgency Episodes per 24 Hours at Week 12: Active Comparator Phase (ACP)/Efficacy Phase (EP)

End point description:

The mean number of urgency episodes per 24 hours were calculated as the total number of urgency episodes divided by the total number of diary days collected at the assessment time point. Number of diary days collected at the assessment time point = number of calendar days when the diary was completed; even if it was not a full 24 hour period. Urgency episodes were defined as urgency marked as 'yes' in the diary. This endpoint was only calculated for subjects with >0 urgency episodes at Baseline and who were sensate. Full analysis set included all subjects who were randomised in the study and received at least 1 dose of study medication and had provided baseline primary endpoint data. Here 'Number of Subjects Analysed' signifies subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Cohort 1, Active Comparator Phase: Fesoterodine 4 mg	Cohort 1, Active Comparator Phase: Fesoterodine 8 mg	Cohort 1, Active Comparator Phase: Oxybutynin	Cohort 2, Efficacy Phase: Fesoterodine 2 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	26	18	26	13

Units: urgency episodes per 24 hours				
least squares mean (confidence interval 95%)	-0.62 (-1.18 to -0.06)	-0.50 (-1.17 to 0.17)	-0.14 (-0.70 to 0.42)	-0.23 (-0.84 to 0.38)

End point values	Cohort 2, Efficacy Phase: Fesoterodine 4 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	9			
Units: urgency episodes per 24 hours				
least squares mean (confidence interval 95%)	-0.62 (-1.35 to 0.12)			

Attachments (see zip file)	Statistical Analysis for Change From Baseline/Endpoint 10

Statistical analyses

Statistical analysis title	Cohort 1, ACP: Fesoterodine 4 mg vs Oxybutynin
Comparison groups	Cohort 1, Active Comparator Phase: Fesoterodine 4 mg v Cohort 1, Active Comparator Phase: Oxybutynin
Number of subjects included in analysis	52
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in LS Mean
Point estimate	-0.48
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.28
upper limit	0.32

Statistical analysis title	Cohort 1, ACP: Fesoterodine 8 mg vs Oxybutynin
Comparison groups	Cohort 1, Active Comparator Phase: Fesoterodine 8 mg v Cohort 1, Active Comparator Phase: Oxybutynin
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in LS Mean
Point estimate	-0.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.24
upper limit	0.52

Secondary: Change From Baseline in Mean Volume Voided per Micturition at Week 12: Active Comparator Phase (ACP)/Efficacy Phase (EP)

End point title	Change From Baseline in Mean Volume Voided per Micturition at Week 12: Active Comparator Phase (ACP)/Efficacy Phase (EP)

End point description:

The mean voided volume per micturition was calculated as sum of voided volume divided by the total number of micturition episodes with a recorded voided volume greater than 0. Full analysis set included all subjects who were randomised in the study and received at least 1 dose of study medication and had provided baseline primary endpoint data. Here 'Number of Subjects Analysed' signifies subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Cohort 1, Active Comparator Phase: Fesoterodine 4 mg	Cohort 1, Active Comparator Phase: Fesoterodine 8 mg	Cohort 1, Active Comparator Phase: Oxybutynin	Cohort 2, Efficacy Phase: Fesoterodine 2 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	15	15	20	8
Units: milliliter per micturition				
least squares mean (confidence interval 95%)	4.10 (-28.05 to 36.24)	19.21 (-12.67 to 51.10)	4.15 (-22.69 to 30.98)	-12.72 (-34.96 to 9.52)

End point values	Cohort 2, Efficacy Phase: Fesoterodine 4 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	10			
Units: milliliter per micturition				
least squares mean (confidence interval 95%)	-8.41 (-28.27 to 11.44)			

Attachments (see zip file)	Statistical Analysis for Change From Baseline/Endpoint 11

Statistical analyses

Statistical analysis title	Cohort 1, ACP: Fesoterodine 4 mg vs Oxybutynin
Comparison groups	Cohort 1, Active Comparator Phase: Fesoterodine 4 mg v Cohort 1, Active Comparator Phase: Oxybutynin
Number of subjects included in analysis	35

Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in LS Mean
Point estimate	-0.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	-42.11
upper limit	42

Statistical analysis title	Cohort 1, ACP: Fesoterodine 8 mg vs Oxybutynin
Comparison groups	Cohort 1, Active Comparator Phase: Fesoterodine 8 mg v Cohort 1, Active Comparator Phase: Oxybutynin
Number of subjects included in analysis	35
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in LS Mean
Point estimate	15.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	-26.5
upper limit	56.63

Secondary: Change From Baseline in Mean Volume Voided per Catheterisation at Week 12: Active Comparator Phase (ACP)/Efficacy Phase (EP)

End point title	Change From Baseline in Mean Volume Voided per Catheterisation at Week 12: Active Comparator Phase (ACP)/Efficacy Phase (EP)

End point description:

The mean volume per catheterisation was calculated as sum of voided volume divided by the total number of catheterisation, with a recorded voided volume greater than 0. Full analysis set included all subjects who were randomised in the study and received at least 1 dose of study medication and had provided baseline primary endpoint data. Here 'Number of Subjects Analysed' signifies subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Cohort 1, Active Comparator Phase: Fesoterodine 4 mg	Cohort 1, Active Comparator Phase: Fesoterodine 8 mg	Cohort 1, Active Comparator Phase: Oxybutynin	Cohort 2, Efficacy Phase: Fesoterodine 2 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	36	32	28	23

Units: milliliter per catheterisation				
least squares mean (confidence interval 95%)	29.47 (-1.38 to 60.32)	47.18 (14.74 to 79.62)	45.90 (11.24 to 80.55)	11.50 (-9.87 to 32.88)

End point values	Cohort 2, Efficacy Phase: Fesoterodine 4 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	25			
Units: milliliter per catheterisation				
least squares mean (confidence interval 95%)	1.74 (-18.76 to 22.23)			

Attachments (see zip file)	Statistical Analysis for Change From Baseline/Endpoint 12

Statistical analyses

Statistical analysis title	Cohort 1, ACP: Fesoterodine 4 mg vs Oxybutynin
Comparison groups	Cohort 1, Active Comparator Phase: Fesoterodine 4 mg v Cohort 1, Active Comparator Phase: Oxybutynin
Number of subjects included in analysis	64
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in LS Mean
Point estimate	-16.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	-63.14
upper limit	30.29

Statistical analysis title	Cohort 1, ACP: Fesoterodine 8 mg vs Oxybutynin
Comparison groups	Cohort 1, Active Comparator Phase: Fesoterodine 8 mg v Cohort 1, Active Comparator Phase: Oxybutynin
Number of subjects included in analysis	60
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in LS Mean
Point estimate	1.28
Confidence interval	
level	95 %
sides	2-sided
lower limit	-46
upper limit	48.57

Secondary: Change From Baseline in Mean Volume Voided per Micturition or Catheterisation at Week 12: Active Comparator Phase (ACP)/Efficacy Phase (EP)

End point title	Change From Baseline in Mean Volume Voided per Micturition or Catheterisation at Week 12: Active Comparator Phase (ACP)/Efficacy Phase (EP)

End point description:

The mean voided volume per micturition or catheterisation was calculated as sum of voided volume divided by the total number of micturitions or catheterisations with a recorded volume voided greater than 0 Full analysis set included all subjects who were randomised in the study and received at least 1 dose of study medication and had provided baseline primary endpoint data. Here 'Number of Subjects Analysed' (N) signifies subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Cohort 1, Active Comparator Phase: Fesoterodine 4 mg	Cohort 1, Active Comparator Phase: Fesoterodine 8 mg	Cohort 1, Active Comparator Phase: Oxybutynin	Cohort 2, Efficacy Phase: Fesoterodine 2 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	39	38	38	24
Units: mL per micturition or catheterisation				
least squares mean (confidence interval 95%)	18.45 (-11.49 to 48.40)	55.55 (25.80 to 85.31)	36.69 (6.95 to 66.43)	7.12 (-11.87 to 26.11)

End point values	Cohort 2, Efficacy Phase: Fesoterodine 4 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	28			
Units: mL per micturition or catheterisation				
least squares mean (confidence interval 95%)	-2.65 (-20.22 to 14.92)			

Attachments (see zip file)	Statistical Analysis for Change From Baseline/Endpoint 13

Statistical analyses

Statistical analysis title	Cohort 1, ACP: Fesoterodine 4 mg vs Oxybutynin
Comparison groups	Cohort 1, Active Comparator Phase: Fesoterodine 4 mg v Cohort 1, Active Comparator Phase: Oxybutynin

Number of subjects included in analysis	77
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in LS Mean
Point estimate	-18.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	-61
upper limit	24.53

Statistical analysis title	Cohort 1, ACP: Fesoterodine 8 mg vs Oxybutynin
Comparison groups	Cohort 1, Active Comparator Phase: Fesoterodine 8 mg v Cohort 1, Active Comparator Phase: Oxybutynin
Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in LS Mean
Point estimate	18.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.93
upper limit	60.65

Secondary: Number of Subjects With Treatment Emergent Adverse Events (AEs) and Serious Adverse Events (SAEs): Active Comparator Phase/Efficacy Phase

End point title	Number of Subjects With Treatment Emergent Adverse Events (AEs) and Serious Adverse Events (SAEs): Active Comparator Phase/Efficacy Phase

End point description:

An AE was any untoward medical occurrence in a subject who received investigational product without regard to possibility of causal relationship. SAE was an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalisation; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly; medically important events. A treatment emergent AE was defined as an event that emerged during the treatment period that was absent before treatment, or worsened during the treatment period relative to the pretreatment state. AEs included both serious and non-serious adverse events. Safety analysis set population for active comparator phase and efficacy phase included all subjects of respective cohorts who received at least 1 dose of study medication in the relevant phase.

End point type	Secondary

End point timeframe:

Baseline up to Week 12

End point values	Cohort 1, Active Comparator Phase: Fesoterodine 4 mg	Cohort 1, Active Comparator Phase: Fesoterodine 8 mg	Cohort 1, Active Comparator Phase: Oxybutynin	Cohort 2, Efficacy Phase: Fesoterodine 2 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42	42	40	28
Units: subjects				
Treatment Emergent AEs	26	20	30	19
Treatment Emergent SAEs	3	2	1	2

End point values	Cohort 2, Efficacy Phase: Fesoterodine 4 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	29			
Units: subjects				
Treatment Emergent AEs	18			
Treatment Emergent SAEs	2			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Treatment Emergent Adverse Events (AEs) and Serious Adverse Events (SAEs): Safety Extension Phase

End point title	Number of Subjects With Treatment Emergent Adverse Events (AEs) and Serious Adverse Events (SAEs): Safety Extension Phase

End point description:

An AE was any untoward medical occurrence in a subject who received investigational product without regard to possibility of causal relationship. SAE was an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalisation; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly; medically important events. A treatment emergent AE was defined as an event that emerged during the treatment period that was absent before treatment, or worsened during the treatment period relative to the pretreatment state. AEs included both serious and non-serious adverse events. Safety analysis set population for safety extension phase included all subjects of respective cohorts who received at least 1 dose of study medication in the relevant phase of the study.

End point type	Secondary

End point timeframe:

Week 12 up to Week 26 (including 2 weeks of follow up after last dose)

End point values	Cohort 1, Safety Extension Phase: Fesoterodine 4 mg	Cohort 1, Safety Extension Phase (SEP): Fesoterodine 8 mg	Cohort 1, SEP: Oxybutynin Then Fesoterodine 4 mg	Cohort 1, SEP: Oxybutynin Then Fesoterodine 8 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	30	37	16	20
Units: subjects				
Treatment emergent AEs	14	13	9	11
Treatment emergent SAEs	0	2	0	0

End point values	Cohort 2, Safety Extension Phase: Fesoterodine 2 mg	Cohort 2, Safety Extension Phase: Fesoterodine 4 mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	20	28		
Units: subjects				
Treatment emergent AEs	11	16		
Treatment emergent SAEs	0	2		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Visual Acuity at Week 12: Active Comparator Phase/Efficacy Phase

End point title	Change From Baseline in Visual Acuity at Week 12: Active Comparator Phase/Efficacy Phase

End point description:

Visual acuity (VA) was assessed using the Snellen method, where logarithm of minimum angle of resolution (logMAR) units were derived from the Snellen ratios. Subjects had to read letters from the chart at a distance of 20 feet/6 meter or 4 meter. VA/Snellen ratio = distance between the chart and subjects divided by distance at which subject was able to see/read chart without impairment; expressed as decimal. logMAR = log10 (1/decimal VA). In this endpoint data have been reported for right and left eye separately. Safety analysis set population for active comparator phase and efficacy phase included all subjects of respective cohorts who received at least 1 dose of study medication in the relevant phase. Here "n": subjects evaluable for this endpoint for specified rows.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Cohort 1, Active Comparator Phase: Fesoterodine 4 mg	Cohort 1, Active Comparator Phase: Fesoterodine 8 mg	Cohort 1, Active Comparator Phase: Oxybutynin	Cohort 2, Efficacy Phase: Fesoterodine 2 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42	42	40	28
Units: logMAR unit				
arithmetic mean (standard deviation)				
Right Eye: Baseline (n=42, 41, 40, 28, 29)	0.09 (± 0.16)	0.11 (± 0.19)	0.03 (± 0.11)	0.15 (± 0.21)
Right Eye: Change at Week 12 (n=37, 40, 40,24,29)	0.01 (± 0.11)	-0.01 (± 0.10)	0.02 (± 0.18)	0.03 (± 0.12)
Left Eye: Baseline (n=42, 42, 40, 28, 29)	0.08 (± 0.16)	0.10 (± 0.17)	0.02 (± 0.13)	0.16 (± 0.21)
Left Eye: Change at Week 12 (n=37, 41, 40, 24, 29)	0.00 (± 0.13)	-0.01 (± 0.10)	0.00 (± 0.13)	-0.02 (± 0.08)

End point values	Cohort 2, Efficacy Phase: Fesoterodine 4 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	29			
Units: logMAR unit				
arithmetic mean (standard deviation)				
Right Eye: Baseline (n=42, 41, 40, 28, 29)	0.10 (± 0.18)			
Right Eye: Change at Week 12 (n=37, 40, 40,24,29)	-0.00 (± 0.09)			
Left Eye: Baseline (n=42, 42, 40, 28, 29)	0.14 (± 0.30)			
Left Eye: Change at Week 12 (n=37, 41, 40, 24, 29)	0.00 (± 0.08)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Visual Acuity at Week 24: Safety Extension Phase

End point title	Change From Baseline in Visual Acuity at Week 24: Safety Extension Phase

End point description:

VA was assessed using the Snellen method, where logMAR units were derived from the Snellen ratios. Subjects had to read letters from the chart at a distance of 20 feet/6 meter or 4 meter. VA/Snellen ratio = distance between the chart and subject divided by distance at which subject was able to see/read chart without impairment; expressed as decimal. logMAR = log10 (1/decimal VA). In this endpoint data have been reported for right and left eye separately. Safety analysis set population for safety extension phase included all subjects of respective cohorts who received at least 1 dose of study medication in the relevant phase. Here "n": subjects evaluable for this endpoint for specified rows.

End point type	Secondary

End point timeframe:

End point values	Cohort 1, Safety Extension Phase: Fesoterodine 4 mg	Cohort 1, SEP: Oxybutynin Then Fesoterodine 4 mg	Cohort 1, SEP: Oxybutynin Then Fesoterodine 8 mg	Cohort 2, Safety Extension Phase: Fesoterodine 2 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	30	16	20	20
Units: logMAR unit				
arithmetic mean (standard deviation)				
Right Eye: Change at Week 24 (n=30,36,16,20,19,28)	0.04 (± 0.17)	-0.01 (± 0.05)	0.02 (± 0.13)	0.00 (± 0.07)
Left Eye: Change at Week 24 (n=30, 37,16,20,19,28)	0.01 (± 0.19)	0.00 (± 0.08)	-0.04 (± 0.09)	-0.02 (± 0.07)

End point values	Cohort 2, Safety Extension Phase: Fesoterodine 4 mg	Cohort 1, Safety Extension Phase: Fesoterodine 8 mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	28	37		
Units: logMAR unit				
arithmetic mean (standard deviation)				
Right Eye: Change at Week 24 (n=30,36,16,20,19,28)	0.01 (± 0.11)	-0.02 (± 0.11)		
Left Eye: Change at Week 24 (n=30, 37,16,20,19,28)	0.03 (± 0.13)	-0.01 (± 0.11)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From baseline in Visual Accommodation at Week 12: Active Comparator Phase/Efficacy Phase

End point title	Change From baseline in Visual Accommodation at Week 12: Active Comparator Phase/Efficacy Phase

End point description:

The visual accommodation was the distance for each eye at which vision became blurred – the mean of triplicate measurements. The subjects focused on a single letter of the 20/40 line of an eye chart and chart was moved slowly towards the subject until letter was blurred. At this point, the distance from eye to letter was measured for each eye. In this endpoint data have been reported for right and left eye separately. Safety analysis set population for active comparator phase and efficacy phase included all subjects of respective cohorts who received at least 1 dose of study medication in the relevant phase. Here "n": subjects evaluable for this endpoint for specified rows.

End point type	Secondary

End point timeframe:

End point values	Cohort 1, Active Comparator Phase: Fesoterodine 4 mg	Cohort 1, Active Comparator Phase: Fesoterodine 8 mg	Cohort 1, Active Comparator Phase: Oxybutynin	Cohort 2, Efficacy Phase: Fesoterodine 2 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42	42	40	28
Units: centimeter				
arithmetic mean (standard deviation)				
Right Eye: Baseline (n=38,39,39,26,28)	11.88 (± 7.39)	15.94 (± 18.64)	9.59 (± 5.05)	9.67 (± 16.71)
Right Eye: Change at Week 12 (n=33,38,39,22,28)	1.74 (± 7.45)	7.77 (± 45.53)	0.50 (± 4.64)	-1.04 (± 6.79)
Left Eye: Baseline (n=39,40,39,26,27)	12.31 (± 8.67)	15.83 (± 17.85)	9.69 (± 5.13)	8.81 (± 14.89)
Left Eye: Change at Week 12 (n=34,39,39,22,27)	0.27 (± 4.29)	5.79 (± 36.75)	0.81 (± 4.78)	-1.45 (± 9.60)

End point values	Cohort 2, Efficacy Phase: Fesoterodine 4 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	29			
Units: centimeter				
arithmetic mean (standard deviation)				
Right Eye: Baseline (n=38,39,39,26,28)	8.17 (± 6.89)			
Right Eye: Change at Week 12 (n=33,38,39,22,28)	1.02 (± 3.89)			
Left Eye: Baseline (n=39,40,39,26,27)	8.04 (± 7.17)			
Left Eye: Change at Week 12 (n=34,39,39,22,27)	0.90 (± 3.38)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From baseline in Visual Accommodation at Week 24: Safety Extension Phase

End point title	Change From baseline in Visual Accommodation at Week 24: Safety Extension Phase

End point description:

The visual accommodation was the distance for each eye at which vision became blurred – the mean of triplicate measurements. The subjects focused on a single letter of the 20/40 line of an eye chart and chart was moved slowly towards the subject until letter was blurred. At this point, the distance from eye to letter was measured for each eye. In this endpoint data have been reported for right and left eye separately. Safety analysis set population for safety extension phase included all subjects of respective

cohorts who received at least 1 dose of study medication in the relevant phase. Here "n": subjects evaluable for this endpoint for specified rows.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	Cohort 1, Safety Extension Phase: Fesoterodine 4 mg	Cohort 1, SEP: Oxybutynin Then Fesoterodine 4 mg	Cohort 1, SEP: Oxybutynin Then Fesoterodine 8 mg	Cohort 2, Safety Extension Phase: Fesoterodine 2 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	30	16	20	20
Units: centimeter				
arithmetic mean (standard deviation)				
Right Eye: Change at Week 24 (n=27,34,16,20,18,27)	0.73 (± 5.47)	1.50 (± 4.80)	0.50 (± 4.30)	-1.35 (± 13.03)
Left Eye: Change at Week 24 (n=28,35,16,20,18,26)	0.90 (± 5.85)	1.66 (± 6.25)	0.58 (± 4.53)	0.43 (± 11.53)

End point values	Cohort 2, Safety Extension Phase: Fesoterodine 4 mg	Cohort 1, Safety Extension Phase: Fesoterodine 8 mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	28	37		
Units: centimeter				
arithmetic mean (standard deviation)				
Right Eye: Change at Week 24 (n=27,34,16,20,18,27)	0.96 (± 4.38)	4.33 (± 28.89)		
Left Eye: Change at Week 24 (n=28,35,16,20,18,26)	1.12 (± 4.20)	3.79 (± 29.81)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Child Behaviour Checklist (CBCL) for Each Domain, T Score at Week 12: Active Comparator Phase/Efficacy Phase

End point title	Change From Baseline in Child Behaviour Checklist (CBCL) for Each Domain, T Score at Week 12: Active Comparator Phase/Efficacy Phase

End point description:

CBCL:questionnaire of 113 items to assess a child's problem behaviours and competencies, answered by parent/caregiver of child. Scale for each item: 0=not true/absent, 1=somewhat or sometimes true/occurs sometime, 2=very true or often true/occurs often. 8 domains/syndrome scales derived: aggressive behaviour (AgB), anxious/depressed (An/De), attention problems (AttP), rule-breaking

behaviour (RuB), social problems (SocP), somatic complaints (SomC), thought problems (ThP), withdrawn (Wd). T-score range for each domain= 50 to 10; lower scores= better outcomes. An/De, Wd and SomC summarised to internalising behaviour (IntB), with a T-score range of 34 to 100, lower scores= better outcomes. Externalising behaviour (ExtB) combined RuB and AgB, with a T-score range of 33 to 100, lower scores= better outcomes. All items combined to form total problem (TotP), with a T-score range of 24 to 100, lower scores= better outcomes. Safety analysis population. n=subjects evaluable for specified rows.

End point type	Secondary
End point timeframe:	
Baseline, Week 12	

End point values	Cohort 1, Active Comparator Phase: Fesoterodine 4 mg	Cohort 1, Active Comparator Phase: Fesoterodine 8 mg	Cohort 1, Active Comparator Phase: Oxybutynin	Cohort 2, Efficacy Phase: Fesoterodine 2 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42	42	40	28
Units: T Score				
arithmetic mean (standard deviation)				
AgB: Baseline (n =42, 41, 40, 28, 29)	53.86 (± 5.67)	54.32 (± 5.88)	54.58 (± 5.75)	54.9 (± 5.25)
AgB: Change at Week 12 (n= 37, 40, 39, 24, 29)	-1.03 (± 3.17)	-0.95 (± 3.71)	-1.28 (± 2.77)	-1.29 (± 3.58)
An/De: Baseline (n= 42, 41, 40, 28, 29)	56.07 (± 6.99)	57.00 (± 8.26)	56.75 (± 7.32)	55.5 (± 6.58)
An/De: Change at Week 12 (n= 37, 40, 39, 24, 29)	-1.73 (± 3.05)	-1.38 (± 5.25)	-1.92 (± 4.66)	-0.79 (± 4.55)
AttP: Baseline (n= 42, 41, 40, 28, 29)	56.29 (± 5.32)	56.66 (± 7.47)	56.30 (± 5.68)	55.4 (± 5.06)
AttP: Change at Week 12 (n= 37, 40, 39, 24, 29)	-1.97 (± 3.79)	-1.40 (± 4.30)	-1.28 (± 3.69)	-1.29 (± 3.61)
RuB: Baseline (n= 42, 41, 40, 28, 29)	53.26 (± 3.52)	53.80 (± 5.53)	53.43 (± 4.96)	54.5 (± 4.96)
RuB: Change at Week 12 (n= 37, 40, 39, 24, 29)	-0.92 (± 2.99)	-0.88 (± 3.91)	-0.72 (± 2.76)	-1.71 (± 4.84)
SocP: Baseline (n= 42, 41, 40, 28, 29)	57.52 (± 5.42)	58.54 (± 9.43)	57.95 (± 7.90)	57.9 (± 6.66)
SocP: Change at Week 12 (n= 37, 40, 39, 24, 29)	-1.35 (± 3.90)	-2.55 (± 4.74)	-0.67 (± 3.73)	-2.21 (± 4.38)
SomC: Baseline (n= 42, 41, 40, 28, 29)	61.14 (± 6.24)	60.46 (± 8.73)	60.58 (± 8.44)	57.1 (± 6.47)
SomC: Change at Week 12 (n= 37, 40, 39, 24, 29)	-0.46 (± 5.99)	-1.28 (± 6.35)	-0.87 (± 7.16)	-0.38 (± 3.97)
ThP: Baseline (n= 42, 41, 40, 28, 29)	55.00 (± 6.19)	53.54 (± 5.93)	56.73 (± 7.64)	51.9 (± 2.81)
ThP: Change at Week 12 (n= 37, 40, 39, 24, 29)	-0.92 (± 4.69)	-0.48 (± 4.25)	-1.59 (± 3.65)	-0.42 (± 1.67)
Wd: Baseline (n= 42, 41, 40, 28, 29)	54.60 (± 5.17)	57.54 (± 8.34)	58.25 (± 7.93)	55.7 (± 5.96)
Wd: Change at Week 12 (n= 37, 40, 39, 24, 29)	0.35 (± 4.70)	-1.25 (± 5.13)	-1.92 (± 5.08)	-1.75 (± 3.97)
ExtB: Baseline (n= 42, 41, 40, 28, 29)	49.48 (± 8.68)	49.46 (± 10.00)	50.10 (± 9.73)	51.1 (± 9.83)
ExtB: Change at Week 12 (n= 37, 40, 39, 24, 29)	-2.08 (± 5.26)	-2.33 (± 5.28)	-1.95 (± 4.62)	-2.63 (± 4.72)
IntB: Baseline (n= 42, 41, 40, 28, 29)	56.45 (± 8.06)	55.93 (± 12.84)	57.25 (± 11.00)	53.9 (± 10.34)
IntB: Change at Week 12 (n= 37, 40, 39, 24, 29)	-2.14 (± 6.46)	-2.35 (± 6.98)	-3.05 (± 7.12)	-1.96 (± 6.53)
TotP: Baseline (n=42, 41, 40, 28, 29)	55.05 (± 8.20)	53.61 (± 11.98)	55.45 (± 10.28)	53.4 (± 10.70)

TotP: Change at Week 12 (n=37, 40, 39, 24, 29)	-2.51 (± 4.63)	-3.23 (± 5.45)	-2.36 (± 4.68)	-2.17 (± 5.05)

End point values	Cohort 2, Efficacy Phase: Fesoterodine 4 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	29			
Units: T Score				
arithmetic mean (standard deviation)				
AgB: Baseline (n =42, 41, 40, 28, 29)	52.8 (± 4.48)			
AgB: Change at Week 12 (n= 37, 40, 39, 24, 29)	-0.03 (± 2.96)			
An/De: Baseline (n= 42, 41, 40, 28, 29)	56.3 (± 6.55)			
An/De: Change at Week 12 (n= 37, 40, 39, 24, 29)	-3.21 (± 5.27)			
AttP: Baseline (n= 42, 41, 40, 28, 29)	55.3 (± 5.74)			
AttP: Change at Week 12 (n= 37, 40, 39, 24, 29)	-1.45 (± 3.41)			
RuB: Baseline (n= 42, 41, 40, 28, 29)	52.3 (± 3.74)			
RuB: Change at Week 12 (n= 37, 40, 39, 24, 29)	-0.10 (± 2.19)			
SocP: Baseline (n= 42, 41, 40, 28, 29)	55.8 (± 5.90)			
SocP: Change at Week 12 (n= 37, 40, 39, 24, 29)	-1.10 (± 3.41)			
SomC: Baseline (n= 42, 41, 40, 28, 29)	58.4 (± 6.55)			
SomC: Change at Week 12 (n= 37, 40, 39, 24, 29)	-1.69 (± 5.90)			
ThP: Baseline (n= 42, 41, 40, 28, 29)	54.9 (± 5.60)			
ThP: Change at Week 12 (n= 37, 40, 39, 24, 29)	-1.38 (± 5.42)			
Wd: Baseline (n= 42, 41, 40, 28, 29)	55.0 (± 7.11)			
Wd: Change at Week 12 (n= 37, 40, 39, 24, 29)	-0.59 (± 4.48)			
ExtB: Baseline (n= 42, 41, 40, 28, 29)	48.0 (± 7.84)			
ExtB: Change at Week 12 (n= 37, 40, 39, 24, 29)	-1.45 (± 4.56)			
IntB: Baseline (n= 42, 41, 40, 28, 29)	54.6 (± 10.14)			
IntB: Change at Week 12 (n= 37, 40, 39, 24, 29)	-3.52 (± 6.38)			
TotP: Baseline (n=42, 41, 40, 28, 29)	52.7 (± 9.37)			
TotP: Change at Week 12 (n=37, 40, 39, 24, 29)	-3.38 (± 4.55)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Child Behaviour Checklist for Each Domain, T Score at Week 24: Safety Extension Phase

End point title	Change From Baseline in Child Behaviour Checklist for Each

	Domain, T Score at Week 24: Safety Extension Phase

End point description:

CBCL:questionnaire of 113 items to assess a child's problem behaviours and competencies, answered by parent/caregiver of child. Scale for each item: 0=not true/absent, 1=somewhat or sometimes true/occurs sometime, 2=very true or often true/occurs often. 8 domains/syndrome scales derived: aggressive behaviour (AgB), anxious/depressed (An/De), attention problems (AttP), rule-breaking behaviour (RuB), social problems (SocP), somatic complaints (SomC), thought problems (ThP), withdrawn (Wd). T-score range for each domain= 50 to 10; lower scores= better outcomes. An/De, Wd and SomC summarised to internalising behaviour (IntB), with a T-score range of 34 to 100, lower scores= better outcomes. Externalising behaviour (ExtB) combined RuB and AgB, with a T-score range of 33 to 100, lower scores= better outcomes. All items combined to form total problem (TotP), with a T-score range of 24 to 100, lower scores= better outcomes. Safety analysis population. n=subjects evaluable for specified rows.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	Cohort 1, Safety Extension Phase: Fesoterodine 4 mg	Cohort 1, SEP: Oxybutynin Then Fesoterodine 4 mg	Cohort 1, SEP: Oxybutynin Then Fesoterodine 8 mg	Cohort 2, Safety Extension Phase: Fesoterodine 2 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	30	16	20	20
Units: T Score				
arithmetic mean (standard deviation)				
AgB: Change at Week 24 (n=29, 36, 16, 20, 20, 28)	-1.59 (± 3.85)	-1.25 (± 3.40)	-2.40 (± 4.89)	-1.70 (± 3.40)
An/De: Change at Week 24 (n=29,36, 16, 20, 20,28)	-3.45 (± 4.86)	-1.50 (± 3.76)	-3.25 (± 5.66)	-2.60 (± 5.24)
AttP: Change at Week 24 (n=29, 36, 16, 20, 20,28)	-2.21 (± 3.99)	-3.38 (± 4.65)	-1.70 (± 3.01)	-1.50 (± 3.15)
RuB: Change at Week 24 (n=29, 36, 16, 20, 20, 28)	-1.59 (± 3.62)	-1.31 (± 4.01)	-0.90 (± 2.36)	-2.15 (± 3.17)
SocP: Change at Week 24 (n=29, 36, 16, 20, 20, 28)	-2.83 (± 4.12)	-3.19 (± 5.79)	-2.65 (± 3.28)	-3.90 (± 4.35)
SomC: Change at Week 24 (n=29, 36,16, 20, 20, 28)	-4.38 (± 6.59)	-1.69 (± 9.20)	-1.50 (± 5.82)	-0.60 (± 3.12)
ThP: Change at Week 24 (n=29, 36, 16, 20, 20, 28)	-3.10 (± 5.45)	-3.25 (± 6.62)	-2.30 (± 3.50)	-1.40 (± 3.00)
Wd: Change at Week 24 (n=29, 36, 16, 20, 20, 28)	-0.69 (± 4.33)	-2.19 (± 3.90)	-4.35 (± 5.24)	-1.80 (± 5.43)
ExtB: Change at Week 24 (n=29, 36,16, 20, 20, 28)	-5.21 (± 8.20)	-1.81 (± 5.42)	-4.15 (± 7.44)	-4.20 (± 5.15)
IntB: Change at Week 24 (n=29,36, 16, 20, 20, 28)	-7.69 (± 7.46)	-3.25 (± 8.10)	-5.35 (± 7.21)	-4.40 (± 6.21)
TotP: Change at Week 24 (n=29,36,16,20,20,28)	-7.03 (± 7.77)	-3.69 (± 6.74)	-4.90 (± 4.78)	-5.20 (± 4.32)

End point values	Cohort 2, Safety Extension Phase: Fesoterodine 4	Cohort 1, Safety Extension Phase: Fesoterodine 8		

	mg	mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	28	37		
Units: T Score				
arithmetic mean (standard deviation)				
AgB: Change at Week 24 (n=29, 36, 16, 20, 20, 28)	-1.86 (± 3.63)	-1.31 (± 4.57)		
An/De: Change at Week 24 (n=29,36, 16, 20, 20,28)	-3.89 (± 4.95)	-2.31 (± 5.64)		
AttP: Change at Week 24 (n=29, 36, 16, 20, 20,28)	-1.71 (± 3.29)	-2.64 (± 5.72)		
RuB: Change at Week 24 (n=29, 36, 16, 20, 20, 28)	-0.36 (± 2.63)	-1.47 (± 5.12)		
SocP: Change at Week 24 (n=29, 36, 16, 20, 20, 28)	-2.36 (± 4.17)	-2.56 (± 4.15)		
SomC: Change at Week 24 (n=29, 36,16, 20, 20, 28)	-1.96 (± 6.77)	-2.64 (± 6.58)		
ThP: Change at Week 24 (n=29, 36, 16, 20, 20, 28)	-1.75 (± 3.99)	-1.03 (± 4.52)		
Wd: Change at Week 24 (n=29, 36, 16, 20, 20, 28)	-0.43 (± 3.75)	-1.50 (± 5.98)		
ExtB: Change at Week 24 (n=29, 36,16, 20, 20, 28)	-4.21 (± 6.86)	-2.89 (± 7.06)		
IntB: Change at Week 24 (n=29,36, 16, 20, 20, 28)	-4.32 (± 6.70)	-4.14 (± 7.62)		
TotP: Change at Week 24 (n=29,36,16,20,20,28)	-5.25 (± 6.22)	-4.44 (± 6.57)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Child Behaviour Checklist for Each Domain, Total Score at Week 12: Active Comparator Phase/Efficacy Phase

End point title	Change From Baseline in Child Behaviour Checklist for Each Domain, Total Score at Week 12: Active Comparator Phase/Efficacy Phase

End point description:

CBCL: questionnaire of 113 items to assess a child's problem behaviours and competencies, answered by parent/caregiver of child. Scale for each item: 0=not true/absent, 1=somewhat or sometimes true/occurs sometime, 2=very true or often true/occurs often.
8 domains/syndrome scales derived; AgB: total score range (TSR) = 0 to 36, An/De: TSR = 0 to 26, AttP: TSR = 0 to 20, RuB: TSR = 0 to 34, SocP: TSR = 0 to 22, SomC: TSR = 0 to 22, ThP: TSR = 0 to 30, Wd. RuB and AgB summarised to ExtB, with a TSR = 0 to 70.
IntB combined An/De, Wd and SomC summarised, with a TSR = 0 to 64. All items combined to TotP, TSR = 0 to 240. Lower scores for each domain, summary and total problem = better outcomes. Safety analysis population. n=subjects evaluable for specified rows.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Cohort 1, Active Comparator Phase: Fesoterodine 4 mg	Cohort 1, Active Comparator Phase: Fesoterodine 8 mg	Cohort 1, Active Comparator Phase: Oxybutynin	Cohort 2, Efficacy Phase: Fesoterodine 2 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42	42	40	28
Units: units on a scale				
arithmetic mean (standard deviation)				
AgB: Baseline (n=42, 41, 40, 28, 29)	4.19 (± 4.39)	4.66 (± 4.46)	4.88 (± 4.35)	5.1 (± 3.95)
AgB: Change at Week 12 (n=37, 40, 39, 24, 29)	-0.62 (± 2.35)	-0.90 (± 2.56)	-0.97 (± 2.08)	-0.92 (± 2.39)
An/De: Baseline (n=42, 41, 40, 28, 29)	3.83 (± 3.33)	4.20 (± 4.06)	4.10 (± 3.53)	3.8 (± 3.15)
An/De: Change at Week 12 (n=37, 40, 39, 24, 29)	-0.97 (± 1.46)	-0.73 (± 2.43)	-1.05 (± 2.26)	-0.58 (± 2.28)
AttP: Baseline (n=42, 41, 40, 28, 29)	4.79 (± 3.18)	4.49 (± 4.11)	4.85 (± 3.33)	4.2 (± 2.78)
AttP: Change at Week 12 (n=37, 40, 39, 24, 29)	-1.05 (± 2.25)	-0.73 (± 2.16)	-0.77 (± 2.03)	-0.71 (± 1.90)
RuB: Baseline (n=42, 41, 40, 28, 29)	1.64 (± 1.48)	1.66 (± 1.98)	1.70 (± 1.87)	1.9 (± 1.63)
RuB: Change at Week 12 (37, 40, 39, 24, 29)	-0.43 (± 1.09)	-0.30 (± 1.36)	-0.38 (± 0.99)	-0.63 (± 1.56)
SocP: Baseline (n=42, 41,40, 28, 29)	3.60 (± 2.30)	4.07 (± 4.12)	3.80 (± 3.36)	3.9 (± 2.99)
SocP: Change at Week 12(n=37, 40, 39, 24, 29)	-0.54 (± 1.54)	-1.13 (± 2.09)	-0.26 (± 1.57)	-0.83 (± 1.86)
SomC: Baseline (n=42, 41, 40, 28, 29)	3.40 (± 2.18)	3.46 (± 3.26)	3.40 (± 3.23)	2.1 (± 1.93)
SomC: Change at Week 12 (n=37, 40, 39 ,24, 29)	-0.05 (± 2.26)	-0.53 (± 2.44)	-0.51 (± 2.64)	-0.04 (± 1.55)
ThP: Baseline (n=42, 41,40, 28, 29)	2.05 (± 2.23)	1.46 (± 2.34)	2.58 (± 2.92)	1.0 (± 1.04)
ThP: Change at Week 12 (n=37, 40, 39, 24, 29)	-0.46 (± 1.69)	-0.10 (± 1.37)	-0.51 (± 1.30)	-0.21 (± 0.72)
Wd: Baseline (n=42, 41, 40, 28, 29)	1.52 (± 1.77)	2.49 (± 2.78)	2.75 (± 2.66)	1.7 (± 1.81)
Wd: Change at Week 12 (n=37, 40, 39, 24, 29)	0.14 (± 1.44)	-0.35 (± 1.59)	-0.64 (± 1.77)	-0.50 (± 1.10)
ExtB Baseline (n=42, 41, 40,28, 29)	5.83 (± 5.23)	6.32 (± 6.14)	6.53 (± 5.87)	6.9 (± 5.16)
ExtB: Change at Week 12 (n=37, 40, 39, 24, 29)	-1.05 (± 2.85)	-1.20 (± 3.42)	-1.31 (± 2.30)	-1.54 (± 3.50)
IntB: Baseline (n= 42, 41, 40, 28, 29)	8.76 (± 5.56)	10.15 (± 8.64)	10.25 (± 7.02)	7.5 (± 5.61)
IntB: Change at Week 12 (n= 37, 40, 39, 24, 29)	-0.89 (± 3.62)	-1.70 (± 5.16)	-2.21 (± 4.35)	-1.13 (± 3.85)
TotP: Baseline (n=42, 41, 40, 28, 29)	31.52 (± 16.84)	31.88 (± 23.78)	34.18 (± 22.16)	29.5 (± 17.41)
TotP: Change at Week 12 (n=37, 40, 39, 24, 29)	-4.92 (± 8.73)	-5.83 (± 12.16)	-5.85 (± 9.77)	-5.33 (± 8.29)

End point values	Cohort 2, Efficacy Phase: Fesoterodine 4 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	29			
Units: units on a scale				
arithmetic mean (standard deviation)				
AgB: Baseline (n=42, 41, 40, 28, 29)	3.5 (± 3.37)			
AgB: Change at Week 12 (n=37, 40, 39, 24, 29)	-0.17 (± 1.85)			

An/De: Baseline (n=42, 41, 40, 28, 29)	4.0 (± 3.35)			
An/De: Change at Week 12 (n=37, 40, 39, 24, 29)	-1.48 (± 2.43)			
AttP: Baseline (n=42, 41, 40, 28, 29)	3.9 (± 3.11)			
AttP: Change at Week 12 (n=37, 40, 39, 24, 29)	-0.83 (± 1.63)			
RuB: Baseline (n=42, 41, 40, 28, 29)	1.0 (± 1.30)			
RuB: Change at Week 12 (37, 40, 39, 24, 29)	0.52 (± 3.45)			
SocP: Baseline (n=42, 41,40, 28, 29)	3.2 (± 2.64)			
SocP: Change at Week 12(n=37, 40, 39, 24, 29)	-0.62 (± 1.52)			
SomC: Baseline (n=42, 41, 40, 28, 29)	2.6 (± 2.16)			
SomC: Change at Week 12 (n=37, 40, 39 ,24, 29)	-0.55 (± 2.03)			
ThP: Baseline (n=42, 41,40, 28, 29)	2.0 (± 1.79)			
ThP: Change at Week 12 (n=37, 40, 39, 24, 29)	-0.45 (± 1.64)			
Wd: Baseline (n=42, 41, 40, 28, 29)	1.6 (± 2.26)			
Wd: Change at Week 12 (n=37, 40, 39, 24, 29)	-0.17 (± 1.39)			
ExtB Baseline (n=42, 41, 40,28, 29)	4.5 (± 4.32)			
ExtB: Change at Week 12 (n=37, 40, 39, 24, 29)	-0.31 (± 2.33)			
IntB: Baseline (n= 42, 41, 40, 28, 29)	8.2 (± 6.13)			
IntB: Change at Week 12 (n= 37, 40, 39, 24, 29)	-2.21 (± 3.91)			
TotP: Baseline (n=42, 41, 40, 28, 29)	27.0 (± 16.59)			
TotP: Change at Week 12 (n=37, 40, 39, 24, 29)	-5.10 (± 7.41)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Child Behaviour Checklist for Each Domain, Total Score at Week 24: Safety Extension Phase

End point title	Change From Baseline in Child Behaviour Checklist for Each Domain, Total Score at Week 24: Safety Extension Phase

End point description:

CBCL: questionnaire of 113 items to assess a child's problem behaviours and competencies, answered by parent/caregiver of child. Scale for each item: 0=not true/absent, 1=somewhat or sometimes true/occurs sometime, 2=very true or often true/occurs often.
8 domains/syndrome scales derived; AgB: total score range (TSR) = 0 to 36, An/De: TSR = 0 to 26, AttP: TSR = 0 to 20, RuB: TSR = 0 to 34, SocP: TSR = 0 to 22, SomC: TSR = 0 to 22, ThP: TSR = 0 to 30, Wd. RuB and AgB summarised to ExtB, with a TSR = 0 to 70.
IntB combined An/De, Wd and SomC summarised, with a TSR = 0 to 64. All items combined to TotP, TSR = 0 to 240. Lower scores for each domain, summary and total problem = better outcomes. Safety analysis population. n=subjects evaluable for specified rows.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	Cohort 1, Safety Extension Phase: Fesoterodine 4 mg	Cohort 1, SEP: Oxybutynin Then Fesoterodine 4 mg	Cohort 1, SEP: Oxybutynin Then Fesoterodine 8 mg	Cohort 2, Safety Extension Phase: Fesoterodine 2 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	29	16	20	20
Units: units on a scale				
arithmetic mean (standard deviation)				
Aggressive behaviour: Change at Week 24	-1.34 (± 2.92)	-0.81 (± 2.43)	-1.75 (± 3.58)	-1.40 (± 2.41)
Anxious/depressed: Change at Week 24	-1.93 (± 2.22)	-1.06 (± 1.88)	-1.60 (± 2.48)	-1.70 (± 2.36)
Attention problems: Change at Week 24	-1.41 (± 2.31)	-1.94 (± 2.35)	-1.25 (± 1.77)	-1.15 (± 1.76)
Rule-breaking behaviour: Change at Week 24	-0.62 (± 1.29)	-0.50 (± 1.21)	-0.55 (± 0.94)	-0.80 (± 1.01)
Social problems: Change at Week 24	-1.28 (± 1.53)	-1.13 (± 2.33)	-1.20 (± 1.36)	-1.65 (± 1.81)
Somatic complaints: Change at Week 24	-1.34 (± 2.22)	-0.88 (± 3.32)	-0.45 (± 1.73)	-0.15 (± 0.88)
Thought problems: Change at Week 24	-1.31 (± 1.95)	-1.06 (± 2.14)	-0.90 (± 1.21)	-0.65 (± 1.04)
Withdrawn: Change at Week 24	-0.24 (± 1.43)	-0.69 (± 1.35)	-1.35 (± 1.66)	-0.45 (± 1.50)
Externalising: Change at Week 24	-1.97 (± 3.50)	-1.19 (± 3.23)	-2.30 (± 4.03)	-2.20 (± 2.84)
Internalising: Change at Week 24	-3.52 (± 4.00)	-2.63 (± 4.65)	-3.40 (± 4.68)	-2.30 (± 3.64)
Total Problems: Change at Week 24	-10.90 (± 11.98)	-9.00 (± 13.45)	-10.10 (± 10.47)	-9.45 (± 7.93)

End point values	Cohort 2, Safety Extension Phase: Fesoterodine 4 mg	Cohort 1, Safety Extension Phase: Fesoterodine 8 mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	28	36		
Units: units on a scale				
arithmetic mean (standard deviation)				
Aggressive behaviour: Change at Week 24	-1.57 (± 2.70)	-1.17 (± 3.10)		
Anxious/depressed: Change at Week 24	-1.75 (± 2.34)	-1.28 (± 2.42)		
Attention problems: Change at Week 24	-0.89 (± 1.69)	-1.36 (± 2.77)		
Rule-breaking behaviour: Change at Week 24	-0.18 (± 0.94)	-0.50 (± 1.65)		
Social problems: Change at Week 24	-1.14 (± 1.74)	-1.19 (± 1.97)		
Somatic complaints: Change at Week 24	-0.68 (± 2.04)	-0.89 (± 2.38)		
Thought problems: Change at Week 24	-0.64 (± 1.28)	-0.36 (± 1.40)		
Withdrawn: Change at Week 24	-0.14 (± 1.04)	-0.44 (± 2.01)		
Externalising: Change at Week 24	-1.79 (± 3.28)	-1.67 (± 4.27)		
Internalising: Change at Week 24	-2.57 (± 3.63)	-2.61 (± 4.95)		
Total Problems: Change at Week 24	-8.39 (± 10.22)	-8.58 (± 12.86)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Grooved Pegboard Test (10 Pegs Group) at Week 12, Time to Completion: Active Comparator Phase/Efficacy Phase

End point title	Change From Baseline in Grooved Pegboard Test (10 Pegs Group) at Week 12, Time to Completion: Active Comparator Phase/Efficacy Phase

End point description:

The grooved pegboard test was a manipulative dexterity test that assessed psychomotor speed, fine motor control, and rapid-visual motor coordination. It consisted of a small board of 25 holes with randomly positioned slots. Pegs with a key along one side must be rotated to match the hole before they can be inserted. Subjects were asked to insert 10 grooved pegs into the holes within the given time limit (up to 300 seconds). The task needs to be completed once for each hand; firstly, using the dominant hand followed by the non-dominant hand. Time taken to complete the test was inversely correlated to the cognitive ability. Safety analysis set analyzed. 10-peg assessment was done only in subjects below age of 9 years. "N": subjects evaluable for this endpoint and "n": subjects evaluable for this endpoint for specified rows. 1 subject inadvertently did the 10-peg test with non-dominant hand and 25-peg test with dominant hand. This subject was counted in 10 peg and 25 peg assessment.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Cohort 1, Active Comparator Phase: Fesoterodine 4 mg	Cohort 1, Active Comparator Phase: Fesoterodine 8 mg	Cohort 1, Active Comparator Phase: Oxybutynin	Cohort 2, Efficacy Phase: Fesoterodine 2 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	9	9	7	18
Units: seconds				
arithmetic mean (standard deviation)				
Dominant hand: Baseline (n=9,8,7,18,20)	61.11 (± 31.66)	56.50 (± 32.09)	46.43 (± 16.28)	69.56 (± 58.52)
Dominant hand: Change at Week 12 (n=7,7,6,15,19)	-7.71 (± 11.06)	10.14 (± 37.18)	-5.33 (± 6.15)	-11.20 (± 41.11)
Non-dominant hand: Baseline (n=9,9,7,17,21)	80.44 (± 41.45)	114.00 (± 89.43)	48.00 (± 15.14)	91.29 (± 110.76)
Non-dominant hand:Change at Week 12(n=7,6,6,14,20)	-21.71 (± 25.44)	15.33 (± 49.28)	-2.00 (± 12.25)	-19.36 (± 81.03)

End point values	Cohort 2, Efficacy Phase: Fesoterodine 4 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	21			
Units: seconds				
arithmetic mean (standard deviation)				
Dominant hand: Baseline (n=9,8,7,18,20)	52.20 (± 31.06)			
Dominant hand: Change at Week 12 (n=7,7,6,15,19)	-10.26 (± 27.21)			

Non-dominant hand: Baseline (n=9,9,7,17,21)	76.29 (± 76.71)			
Non-dominant hand:Change at Week 12(n=7,6,6,14,20)	-3.25 (± 22.53)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Grooved Pegboard Test (10 Pegs Group) at Week 24, Time to Completion: Safety Extension Phase

End point title	Change From Baseline in Grooved Pegboard Test (10 Pegs Group) at Week 24, Time to Completion: Safety Extension Phase

End point description:

The grooved pegboard test was a manipulative dexterity test that assessed psychomotor speed, fine motor control, and rapid-visual motor coordination. It consisted of a small board of 25 holes with randomly positioned slots. Pegs with a key along one side must be rotated to match the hole before they can be inserted. Subjects were asked to insert 10 grooved pegs into the holes within the given time limit (up to 300 seconds). The task needs to be completed once for each hand; firstly, using the dominant hand followed by the non-dominant hand. Time taken to complete the test was inversely correlated to the cognitive ability. Subjects were assigned to either a 10- or 25-peg assessment based on their age. 10-peg assessment was done on subjects below age of 9 years. Safety analysis set population for safety extension phase analysed. Here "N": subjects evaluable for this endpoint and "n": subjects evaluable for this endpoint for specified rows.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	Cohort 1, Safety Extension Phase: Fesoterodine 4 mg	Cohort 1, SEP: Oxybutynin Then Fesoterodine 4 mg	Cohort 1, SEP: Oxybutynin Then Fesoterodine 8 mg	Cohort 2, Safety Extension Phase: Fesoterodine 2 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3	2	3	15
Units: seconds				
arithmetic mean (standard deviation)				
Dominant hand:Change at Week 24(n=3,7,2,3,15,18)	-11.33 (± 9.07)	-2.00 (± 8.49)	-6.33 (± 3.06)	-7.07 (± 6.80)
Nondominant hand:Change at Week24(n=3,6,2,3,14,19)	-2.00 (± 13.75)	1.50 (± 10.61)	-11.00 (± 5.00)	-9.14 (± 14.33)

End point values	Cohort 2, Safety Extension Phase: Fesoterodine 4 mg	Cohort 1, Safety Extension Phase: Fesoterodine 8 mg		
Subject group type	Subject analysis set	Subject analysis set		

Number of subjects analysed	19	7		
Units: seconds				
arithmetic mean (standard deviation)				
Dominant hand:Change at Week 24(n=3,7,2,3,15,18)	-15.00 (± 28.54)	-3.71 (± 22.94)		
Nondominant hand:Change at Week24(n=3,6,2,3,14,19)	-18.47 (± 38.13)	-4.00 (± 29.09)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Grooved Pegboard Test (25 Pegs Group) at Week 12, Time to Completion: Active Comparator Phase/Efficacy Phase

End point title	Change From Baseline in Grooved Pegboard Test (25 Pegs Group) at Week 12, Time to Completion: Active Comparator Phase/Efficacy Phase

End point description:

The grooved pegboard test was a manipulative dexterity test that assessed psychomotor speed, fine motor control, and rapid-visual motor coordination. It consisted of a small board of 25 holes with randomly positioned slots. Pegs with a key along one side must be rotated to match the hole before they can be inserted. Subjects were asked to insert 25 grooved pegs into the holes within the given time limit (up to 300 seconds). The task needs to be completed once for each hand; firstly, using the dominant hand followed by the non-dominant hand. Safety analysis set analyzed. 10-peg assessment was done only in subjects below age of 9 years. "N": subjects evaluable for this endpoint and "n": subjects evaluable for this endpoint for specified rows. 1 subject inadvertently did the 10-peg test with non-dominant hand and 25-peg test with dominant hand. This subject was counted in 10 peg and 25 peg assessment.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Cohort 1, Active Comparator Phase: Fesoterodine 4 mg	Cohort 1, Active Comparator Phase: Fesoterodine 8 mg	Cohort 1, Active Comparator Phase: Oxybutynin	Cohort 2, Efficacy Phase: Fesoterodine 2 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	33	34	33	10
Units: seconds				
arithmetic mean (standard deviation)				
Dominant hand: Baseline (n=33,34,33,10,9)	88.85 (± 24.22)	92.15 (± 40.51)	82.64 (± 24.32)	106.7 (± 64.07)
Dominant hand: Change at Week 12 (n=30,33,33,8,9)	-5.40 (± 10.43)	-8.88 (± 20.76)	1.21 (± 11.87)	-14.38 (± 25.90)
Non-dominant hand: Baseline (33, 32,33,10,8)	110.61 (± 59.63)	109.00 (± 49.75)	92.94 (± 25.05)	130.30 (± 83.58)
Nondominant hand:Change at Week 12(n=30,31,33,8,8)	-9.10 (± 19.94)	-4.10 (± 10.79)	-1.97 (± 14.00)	-13.50 (± 18.81)

End point values	Cohort 2, Efficacy Phase: Fesoterodine 4 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	9			
Units: seconds				
arithmetic mean (standard deviation)				
Dominant hand: Baseline (n=33,34,33,10,9)	124.7 (± 71.99)			
Dominant hand: Change at Week 12 (n=30,33,33,8,9)	-18.44 (± 32.23)			
Non-dominant hand: Baseline (33, 32,33,10,8)	126.1 (± 48.93)			
Nondominant hand:Change at Week 12(n=30,31,33,8,8)	-12.50 (± 20.30)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Grooved Pegboard Test (25 Pegs Group) at Weeks 24, Time to Completion: Safety Extension Phase

End point title	Change From Baseline in Grooved Pegboard Test (25 Pegs Group) at Weeks 24, Time to Completion: Safety Extension Phase

End point description:

The grooved pegboard test was a manipulative dexterity test that assessed psychomotor speed, fine motor control, and rapid-visual motor coordination. It consisted of a small board of 25 holes with randomly positioned slots. Pegs with a key along one side must be rotated to match the hole before they can be inserted. Subjects were asked to insert 25 grooved pegs into the holes within the given time limit (up to 300 seconds). The task needs to be completed once for each hand; firstly, using the dominant hand followed by the non-dominant hand. Time taken to complete the test was inversely correlated to the cognitive ability. Subjects were assigned to either a 10- or 25-peg assessment based on their age. 25-peg assessment was done on subjects of age 9 years and above. Safety analysis set population for safety extension phase analysed. Here "N": subjects evaluable for this endpoint and "n": subjects evaluable for this endpoint for specified rows.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	Cohort 1, Safety Extension Phase: Fesoterodine 4 mg	Cohort 1, SEP: Oxybutynin Then Fesoterodine 4 mg	Cohort 1, SEP: Oxybutynin Then Fesoterodine 8 mg	Cohort 2, Safety Extension Phase: Fesoterodine 2 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	25	14	16	5
Units: seconds				
arithmetic mean (standard deviation)				
Dominant hand: Change at Week 24;n=25,30,14,16,5,9	-8.20 (± 11.67)	-5.71 (± 9.55)	-7.00 (± 13.25)	-38.20 (± 31.67)

Nondominant hand:Change Week24;n=25,28,14,15,5,8	-9.24 (± 15.79)	-3.79 (± 11.89)	-11.87 (± 14.15)	-38.00 (± 29.35)

End point values	Cohort 2, Safety Extension Phase: Fesoterodine 4 mg	Cohort 1, Safety Extension Phase: Fesoterodine 8 mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	9	30		
Units: seconds				
arithmetic mean (standard deviation)				
Dominant hand: Change at Week 24;n=25,30,14,16,5,9	-17.00 (± 33.16)	-12.27 (± 18.28)		
Nondominant hand:Change Week24;n=25,28,14,15,5,8	-15.50 (± 29.11)	-8.46 (± 10.42)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Grooved Pegboard Test (10 Pegs Group) at Week 12, Number of Pegs Dropped: Active Comparator Phase/Efficacy Phase

End point title	Change From Baseline in Grooved Pegboard Test (10 Pegs Group) at Week 12, Number of Pegs Dropped: Active Comparator Phase/Efficacy Phase

End point description:

The grooved pegboard test was a manipulative dexterity test that assessed psychomotor speed, fine motor control, and rapid-visual motor coordination. It consisted of a small board of 25 holes with randomly positioned slots. Pegs with a key along one side must be rotated to match the hole before they can be inserted. Subjects were asked to insert 10 grooved pegs into the holes within the given time limit (up to 300 seconds). The task needs to be completed once for each hand; firstly, using the dominant hand followed by the non-dominant hand. Time taken to complete the test was inversely correlated to the cognitive ability. Safety analysis set analyzed. 10-peg assessment was done only in subjects below age of 9 years. "N": subjects evaluable for this endpoint and "n": subjects evaluable for this endpoint for specified rows. 1 subject inadvertently did the 10-peg test with non-dominant hand and 25-peg test with dominant hand. This subject was counted in 10 peg and 25 peg assessment.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Cohort 1, Active Comparator Phase: Fesoterodine 4 mg	Cohort 1, Active Comparator Phase: Fesoterodine 8 mg	Cohort 1, Active Comparator Phase: Oxybutynin	Cohort 2, Efficacy Phase: Fesoterodine 2 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	9	9	7	18
Units: pegs				

arithmetic mean (standard deviation)				
Dominant hand: Baseline (n=9,8,7, 18,20)	0.11 (± 0.33)	0.75 (± 1.75)	0.29 (± 0.49)	0.39 (± 1.24)
Dominant hand: Change at Week 12 (n=7,7,6,15,19)	0.29 (± 0.76)	0.57 (± 1.13)	-0.17 (± 0.75)	0.00 (± 1.77)
Non-dominant hand: Baseline (n=9, 9,7,17,21)	0.44 (± 0.53)	1.22 (± 2.28)	0.00 (± 0.00)	0.35 (± 0.86)
Non-dominant hand:Change at Week 12(n=7,6,6,14,20)	0.43 (± 1.27)	1.00 (± 2.00)	0.17 (± 0.41)	0.00 (± 0.68)

End point values	Cohort 2, Efficacy Phase: Fesoterodine 4 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	21			
Units: pegs				
arithmetic mean (standard deviation)				
Dominant hand: Baseline (n=9,8,7, 18,20)	0.10 (± 0.45)			
Dominant hand: Change at Week 12 (n=7,7,6,15,19)	0.05 (± 0.52)			
Non-dominant hand: Baseline (n=9, 9,7,17,21)	0.76 (± 2.26)			
Non-dominant hand:Change at Week 12(n=7,6,6,14,20)	0.60 (± 3.45)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Grooved Pegboard Test (10 Pegs Group) at Week 24, Number of Pegs Dropped: Safety Extension Phase

End point title	Change From Baseline in Grooved Pegboard Test (10 Pegs Group) at Week 24, Number of Pegs Dropped: Safety Extension Phase

End point description:

The grooved pegboard test was a manipulative dexterity test that assessed psychomotor speed, fine motor control, and rapid-visual motor coordination. It consisted of a small board of 25 holes with randomly positioned slots. Pegs with a key along one side must be rotated to match the hole before they can be inserted. Subjects were asked to insert 10 grooved pegs into the holes within the given time limit (up to 300 seconds). The task needs to be completed once for each hand; firstly, using the dominant hand followed by the non-dominant hand. Number of pegs dropped while putting in the holes were measured. Subjects were assigned to either a 10- or 25-peg assessment based on their age. 10-peg assessment was done on subjects below age of 9 years. Safety analysis set population for safety extension phase analysed. Here "N": subjects evaluable for this endpoint and "n": subjects evaluable for this endpoint for specified rows.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	Cohort 1, Safety Extension Phase: Fesoterodine 4 mg	Cohort 1, SEP: Oxybutynin Then Fesoterodine 4 mg	Cohort 1, SEP: Oxybutynin Then Fesoterodine 8 mg	Cohort 2, Safety Extension Phase: Fesoterodine 2 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3	2	3	15
Units: pegs				
arithmetic mean (standard deviation)				
Dominant hand: Change at week 24 (n=3,7,2,3,15,18)	0.33 (± 0.58)	0.00 (± 0.00)	-0.33 (± 0.58)	-0.27 (± 1.39)
Nondominant hand: Change Week 24;n=3,6,2,3,14,19	1.33 (± 2.31)	0.50 (± 0.71)	0.00 (± 0.00)	-0.36 (± 0.74)

End point values	Cohort 2, Safety Extension Phase: Fesoterodine 4 mg	Cohort 1, Safety Extension Phase: Fesoterodine 8 mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	19	7		
Units: pegs				
arithmetic mean (standard deviation)				
Dominant hand: Change at week 24 (n=3,7,2,3,15,18)	-0.06 (± 0.54)	0.43 (± 0.79)		
Nondominant hand: Change Week 24;n=3,6,2,3,14,19	0.11 (± 3.45)	0.00 (± 1.10)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Grooved Pegboard Test (25 Pegs Group) at Week 12, Number of Pegs Dropped: Active Comparator Phase/Efficacy Phase

End point title	Change From Baseline in Grooved Pegboard Test (25 Pegs Group) at Week 12, Number of Pegs Dropped: Active Comparator Phase/Efficacy Phase

End point description:

The grooved pegboard test was a manipulative dexterity test that assessed psychomotor speed, fine motor control, and rapid-visual motor coordination. It consisted of a small board of 25 holes with randomly positioned slots. Pegs with a key along one side must be rotated to match the hole before they can be inserted. Subjects were asked to insert 25 grooved pegs into the holes within the given time limit (up to 300 seconds). The task needs to be completed once for each hand; firstly, using the dominant hand followed by the non-dominant hand. Safety analysis set analyzed. 10-peg assessment was done only in subjects below age of 9 years. "N": subjects evaluable for this endpoint and "n": subjects evaluable for this endpoint for specified rows. 1 subject inadvertently did the 10-peg test with non-dominant hand and 25-peg test with dominant hand. This subject was counted in 10 peg and 25 peg assessment.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Cohort 1, Active Comparator Phase: Fesoterodine 4 mg	Cohort 1, Active Comparator Phase: Fesoterodine 8 mg	Cohort 1, Active Comparator Phase: Oxybutynin	Cohort 2, Efficacy Phase: Fesoterodine 2 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	33	34	33	10
Units: pegs				
arithmetic mean (standard deviation)				
Dominant hand: Baseline (n=33,34,33,10,9)	0.45 (± 1.20)	0.24 (± 0.50)	0.24 (± 0.66)	0.10 (± 0.32)
Dominant hand: Change at Week 12 (n=30,33,33,8,9)	0.00 (± 1.05)	-0.18 (± 0.58)	0.09 (± 0.77)	0.00 (± 0.53)
Non-dominant hand: Baseline (n=33,32,33,10,8)	0.91 (± 2.36)	0.28 (± 0.46)	0.36 (± 0.78)	0.40 (± 0.97)
Non-dominant hand:Change at Week 12;n=30,31,33,8,8	-0.33 (± 1.60)	0.06 (± 1.03)	0.21 (± 1.78)	0.13 (± 0.35)

End point values	Cohort 2, Efficacy Phase: Fesoterodine 4 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	9			
Units: pegs				
arithmetic mean (standard deviation)				
Dominant hand: Baseline (n=33,34,33,10,9)	0.11 (± 0.33)			
Dominant hand: Change at Week 12 (n=30,33,33,8,9)	0.44 (± 1.33)			
Non-dominant hand: Baseline (n=33,32,33,10,8)	0.13 (± 0.35)			
Non-dominant hand:Change at Week 12;n=30,31,33,8,8	0.00 (± 0.00)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Grooved Pegboard Test (25 Pegs Group) at Week 24, Number of Pegs Dropped: Safety Extension Phase

End point title	Change From Baseline in Grooved Pegboard Test (25 Pegs Group) at Week 24, Number of Pegs Dropped: Safety Extension Phase

End point description:

The grooved pegboard test was a manipulative dexterity test that assessed psychomotor speed, fine motor control, and rapid-visual motor coordination. It consisted of a small board of 25 holes with randomly positioned slots. Pegs with a key along one side must be rotated to match the hole before they

can be inserted. Subjects were asked to insert 25 grooved pegs into the holes within the given time limit (up to 300 seconds). The task needs to be completed once for each hand; firstly, using the dominant hand followed by the non-dominant hand. Number of pegs dropped while putting in the holes were measured. Subjects were assigned to either a 10- or 25-peg assessment based on their age. 25-peg assessment was done on subjects of age 9 years and above. Safety analysis set population for safety extension phase analysed. Here "N": subjects evaluable for this endpoint and "n": subjects evaluable for this endpoint for specified rows.

End point type	Secondary
End point timeframe:	
Baseline, Week 24	

End point values	Cohort 1, Safety Extension Phase: Fesoterodine 4 mg	Cohort 1, SEP: Oxybutynin Then Fesoterodine 4 mg	Cohort 1, SEP: Oxybutynin Then Fesoterodine 8 mg	Cohort 2, Safety Extension Phase: Fesoterodine 2 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	25	14	16	5
Units: pegs				
arithmetic mean (standard deviation)				
Dominant hand: Change at Week 24;n=25,30,14,16,5,9	0.00 (± 0.87)	0.14 (± 0.36)	0.25 (± 1.24)	0.00 (± 0.00)
Nondominant hand:Change Week24;n=25,28,14,15,5,8	-0.28 (± 2.17)	0.00 (± 0.39)	0.27 (± 1.67)	0.60 (± 0.89)

End point values	Cohort 2, Safety Extension Phase: Fesoterodine 4 mg	Cohort 1, Safety Extension Phase: Fesoterodine 8 mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	9	30		
Units: pegs				
arithmetic mean (standard deviation)				
Dominant hand: Change at Week 24;n=25,30,14,16,5,9	0.44 (± 1.33)	0.63 (± 4.63)		
Nondominant hand:Change Week24;n=25,28,14,15,5,8	-0.13 (± 0.35)	0.68 (± 4.79)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Grooved Pegboard Test (10 Pegs Group) at Week 12, Number of Pegs Placed Correctly: Active Comparator Phase/Efficacy Phase

End point title	Change From Baseline in Grooved Pegboard Test (10 Pegs Group) at Week 12, Number of Pegs Placed Correctly: Active

	Comparator Phase/Efficacy Phase

End point description:

The grooved pegboard test was a manipulative dexterity test that assessed psychomotor speed, fine motor control, and rapid-visual motor coordination. It consisted of a small board of 25 holes with randomly positioned slots. Pegs with a key along one side must be rotated to match the hole before they can be inserted. Subjects were asked to insert 10 grooved pegs into the holes within the given time limit (up to 300 seconds). The task needs to be completed once for each hand; firstly, using the dominant hand followed by the non-dominant hand. Time taken to complete the test was inversely correlated to the cognitive ability. Safety analysis set analyzed. 10-peg assessment was done only in subjects below age of 9 years. "N": subjects evaluable for this endpoint and "n": subjects evaluable for this endpoint for specified rows. 1 subject inadvertently did the 10-peg test with non-dominant hand and 25-peg test with dominant hand. This subject was counted in 10 peg and 25 peg assessment.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Cohort 1, Active Comparator Phase: Fesoterodine 4 mg	Cohort 1, Active Comparator Phase: Fesoterodine 8 mg	Cohort 1, Active Comparator Phase: Oxybutynin	Cohort 2, Efficacy Phase: Fesoterodine 2 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	9	9	7	18
Units: pegs				
arithmetic mean (standard deviation)				
Dominant hand: Baseline (n=9,8,7,18,20)	9.56 (± 1.01)	9.38 (± 1.77)	10.00 (± 0.00)	9.89 (± 0.47)
Dominant hand: Change at Week 12 (n=7,7,6,15,19)	-0.29 (± 0.76)	0.00 (± 0.00)	0.00 (± 0.00)	0.00 (± 0.38)
Non-dominant hand: Baseline (n=9, 9,7,17,21)	9.56 (± 1.01)	9.00 (± 2.35)	10.00 (± 0.00)	9.82 (± 0.73)
Nondominant hand:Change at Week 12 (n=7,6,6,14,20)	-0.57 (± 1.13)	0.00 (± 0.00)	0.00 (± 0.00)	-0.07 (± 0.62)

End point values	Cohort 2, Efficacy Phase: Fesoterodine 4 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	21			
Units: pegs				
arithmetic mean (standard deviation)				
Dominant hand: Baseline (n=9,8,7,18,20)	10.0 (± 0.00)			
Dominant hand: Change at Week 12 (n=7,7,6,15,19)	-0.11 (± 0.46)			
Non-dominant hand: Baseline (n=9, 9,7,17,21)	9.62 (± 1.20)			
Nondominant hand:Change at Week 12 (n=7,6,6,14,20)	0.00 (± 0.32)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Grooved Pegboard Test (10 Pegs Group) at Week 24, Number of Pegs Placed Correctly: Safety Extension Phase

End point title	Change From Baseline in Grooved Pegboard Test (10 Pegs Group) at Week 24, Number of Pegs Placed Correctly: Safety Extension Phase

End point description:

The grooved pegboard test was a manipulative dexterity test that assessed psychomotor speed, fine motor control, and rapid-visual motor coordination. It consisted of a small board of 25 holes with randomly positioned slots. Pegs with a key along one side must be rotated to match the hole before they can be inserted. Subjects were asked to insert 10 grooved pegs into the holes within the given time limit (up to 300 seconds). The task needs to be completed once for each hand; firstly, using the dominant hand followed by the non-dominant hand. Number of pegs placed correctly in hole was measured. Subjects were assigned to either a 10- or 25-peg assessment based on their age. 10-peg assessment was done on subjects below age of 9 years. Safety analysis set population for safety extension phase analysed. Here "N": subjects evaluable for this endpoint and "n": subjects evaluable for this endpoint for specified rows.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	Cohort 1, Safety Extension Phase: Fesoterodine 4 mg	Cohort 1, SEP: Oxybutynin Then Fesoterodine 4 mg	Cohort 1, SEP: Oxybutynin Then Fesoterodine 8 mg	Cohort 2, Safety Extension Phase: Fesoterodine 2 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3	2	3	15
Units: pegs				
arithmetic mean (standard deviation)				
Dominant hand: Change at Week 24 (n=3,7,2,3,15,18)	-0.33 (± 0.58)	0.00 (± 0.00)	0.00 (± 0.00)	0.07 (± 0.26)
Nondominant hand:Change at Week 24;n=3,6,2,3,14,19	-1.33 (± 2.31)	0.00 (± 0.00)	0.00 (± 0.00)	0.14 (± 0.53)

End point values	Cohort 2, Safety Extension Phase: Fesoterodine 4 mg	Cohort 1, Safety Extension Phase: Fesoterodine 8 mg		
Subject group type	Subject analysis set	Subject analysis set		

Number of subjects analysed	19	7		
Units: pegs				
arithmetic mean (standard deviation)				
Dominant hand: Change at Week 24 (n=3,7,2,3,15,18)	0.00 (± 0.00)	0.00 (± 0.00)		
Nondominant hand:Change at Week 24;n=3,6,2,3,14,19	0.21 (± 0.92)	0.00 (± 0.00)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Grooved Pegboard Test (25 Pegs Group) at Weeks 12, Number of Pegs Placed Correctly: Active Comparator Phase/Efficacy Phase

End point title	Change From Baseline in Grooved Pegboard Test (25 Pegs Group) at Weeks 12, Number of Pegs Placed Correctly: Active Comparator Phase/Efficacy Phase

End point description:

The grooved pegboard test was a manipulative dexterity test that assessed psychomotor speed, fine motor control, and rapid-visual motor coordination. It consisted of a small board of 25 holes with randomly positioned slots. Pegs with a key along one side must be rotated to match the hole before they can be inserted. Subjects were asked to insert 25 grooved pegs into the holes within the given time limit (up to 300 seconds). The task needs to be completed once for each hand; firstly, using the dominant hand followed by the non-dominant hand. Safety analysis set analyzed. 10-peg assessment was done only in subjects below age of 9 years. "N": subjects evaluable for this endpoint and "n": subjects evaluable for this endpoint for specified rows. 1 subject inadvertently did the 10-peg test with non-dominant hand and 25-peg test with dominant hand. This subject was counted in 10 peg and 25 peg assessment.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Cohort 1, Active Comparator Phase: Fesoterodine 4 mg	Cohort 1, Active Comparator Phase: Fesoterodine 8 mg	Cohort 1, Active Comparator Phase: Oxybutynin	Cohort 2, Efficacy Phase: Fesoterodine 2 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	33	34	33	10
Units: pegs				
arithmetic mean (standard deviation)				
Dominant hand: Baseline (n=33,34,33,10,9)	25.00 (± 0.00)	24.56 (± 1.89)	25.00 (± 0.00)	25.00 (± 0.00)
Dominant hand: Change at Week 12 (n=30,33,33,8,9)	-0.07 (± 0.25)	0.42 (± 1.77)	-0.12 (± 0.70)	-0.13 (± 0.35)
Non-dominant hand: Baseline (n=33, 32,33,10,8)	24.45 (± 2.09)	24.75 (± 0.92)	24.88 (± 0.42)	24.50 (± 1.58)
Nondominant hand: Change at Week 12;n=30,31,33,8,8	0.53 (± 2.19)	0.26 (± 0.93)	0.03 (± 0.30)	0.63 (± 1.77)

End point values	Cohort 2, Efficacy Phase: Fesoterodine 4 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	9			
Units: pegs				
arithmetic mean (standard deviation)				
Dominant hand: Baseline (n=33,34,33,10,9)	23.22 (± 3.83)			
Dominant hand: Change at Week 12 (n=30,33,33,8,9)	0.11 (± 2.76)			
Non-dominant hand: Baseline (n=33, 32,33,10,8)	24.25 (± 1.75)			
Nondominant hand: Change at Week 12;n=30,31,33,8,8	-0.63 (± 1.77)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Grooved Pegboard Test (25 Pegs Group) at Week 24, Number of Pegs Placed Correctly: Safety Extension Phase

End point title	Change From Baseline in Grooved Pegboard Test (25 Pegs Group) at Week 24, Number of Pegs Placed Correctly: Safety Extension Phase

End point description:

The grooved pegboard test was a manipulative dexterity test that assessed psychomotor speed, fine motor control, and rapid-visual motor coordination. It consisted of a small board of 25 holes with randomly positioned slots. Pegs with a key along one side must be rotated to match the hole before they can be inserted. Subjects were asked to insert 25 grooved pegs into the holes within the given time limit (up to 300 seconds). The task needs to be completed once for each hand; firstly, using the dominant hand followed by the non-dominant hand. Number of pegs placed correctly in hole was measured. Subjects were assigned to either a 10- or 25-peg assessment based on their age. 25-peg assessment was done on subjects of age 9 years and above. Safety analysis set population for safety extension phase analysed. Here "N": subjects evaluable for this endpoint and "n": subjects evaluable for this endpoint for specified rows.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	Cohort 1, Safety Extension Phase: Fesoterodine 4 mg	Cohort 1, SEP: Oxybutynin Then Fesoterodine 4 mg	Cohort 1, SEP: Oxybutynin Then Fesoterodine 8 mg	Cohort 2, Safety Extension Phase: Fesoterodine 2 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	25	14	16	5
Units: pegs				

arithmetic mean (standard deviation)				
Dominant hand: Change at Week 24;n=25,30,14,16,5,9	0.00 (± 0.00)	0.00 (± 0.00)	0.00 (± 0.00)	0.00 (± 0.00)
Nondominant hand:Change Week24;n=25,28,14,15,5,8	0.60 (± 2.40)	0.14 (± 0.66)	0.00 (± 0.00)	0.60 (± 2.61)

End point values	Cohort 2, Safety Extension Phase: Fesoterodine 4 mg	Cohort 1, Safety Extension Phase: Fesoterodine 8 mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	9	30		
Units: pegs				
arithmetic mean (standard deviation)				
Dominant hand: Change at Week 24;n=25,30,14,16,5,9	0.11 (± 2.76)	0.50 (± 2.01)		
Nondominant hand:Change Week24;n=25,28,14,15,5,8	-0.50 (± 1.85)	0.21 (± 0.96)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects Meeting Criteria for Vital Signs Values From Baseline Through Week 12: Active Comparator/Efficacy Phase

End point title	Number of subjects Meeting Criteria for Vital Signs Values From Baseline Through Week 12: Active Comparator/Efficacy Phase

End point description:

Criteria for vital signs: 1) a) systolic blood pressure (SBP) of <90 millimeter of mercury (mmHg), b) change >=30 mmHg increase, c) change >=30 mmHg decrease; 2) a) diastolic blood pressure (DBP) of <50 mmHg, b) change >=20 mmHg increase, c) change >=20 mmHg decrease; 3) a) pulse rate value of <40 beats per minute (bpm), b) pulse rate value >120 bpm. Safety analysis set population for active comparator phase and efficacy phase: all subjects of respective cohorts who received at least 1 dose of study medication in relevant phase. Here "N": subjects evaluable for this end point

End point type	Secondary

End point timeframe:

Baseline up to Week 12

End point values	Cohort 1, Active Comparator Phase: Fesoterodine 4 mg	Cohort 1, Active Comparator Phase: Fesoterodine 8 mg	Cohort 1, Active Comparator Phase: Oxybutynin	Cohort 2, Efficacy Phase: Fesoterodine 2 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	40	41	40	24
Units: subjects				
SBP: <90 mmHg	2	2	0	7

SBP: Change >= 30 mmHg increase	1	2	1	0
SBP: Change >= 30 mmHg decrease	1	0	0	0
DBP: <50 mmHg	2	1	2	3
DBP: Change >= 20 mmHg increase	1	2	1	3
DBP: Change >= 20 mmHg decrease	1	1	1	2
Pulse rate: <40 bpm	0	0	0	0
Pulse rate: >120 bpm	2	4	0	2

End point values	Cohort 2, Efficacy Phase: Fesoterodine 4 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	29			
Units: subjects				
SBP: <90 mmHg	4			
SBP: Change >= 30 mmHg increase	1			
SBP: Change >= 30 mmHg decrease	0			
DBP: <50 mmHg	1			
DBP: Change >= 20 mmHg increase	4			
DBP: Change >= 20 mmHg decrease	0			
Pulse rate: <40 bpm	0			
Pulse rate: >120 bpm	3			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects Meeting Criteria for Vital Signs Values From Baseline Through Week 24: Safety Extension Phase

End point title	Number of Subjects Meeting Criteria for Vital Signs Values From Baseline Through Week 24: Safety Extension Phase

End point description:

Criteria for vital signs: 1) a) systolic blood pressure (SBP) of <90 mmHg, b) change >=30 mmHg increase, c) change >=30 mmHg decrease; 2) a) diastolic blood pressure (DBP) of <50 mmHg, b) change >=20 mmHg increase, c) change >=20 mmHg decrease; 3) a) pulse rate value of <40 bpm, b) pulse rate value >120 bpm. Safety analysis set population for safety extension phase included all subjects of respective cohorts who received at least 1 dose of study medication in the relevant phase of the study.

End point type	Secondary

End point timeframe:

Baseline up to Week 24

End point values	Cohort 1, Safety Extension Phase: Fesoterodine 4 mg	Cohort 1, SEP: Oxybutynin Then Fesoterodine 4 mg	Cohort 1, SEP: Oxybutynin Then Fesoterodine 8 mg	Cohort 2, Safety Extension Phase: Fesoterodine 2 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	30	16	20	20
Units: subjects				
SBP: <90 mmHg	0	2	1	4
SBP: Change >= 30 mmHg increase	1	0	0	0
SBP: Change >= 30 mmHg decrease	0	0	0	0
DBP: <50 mmHg	0	0	0	2
DBP: Change >= 20 mmHg increase	1	0	0	1
DBP: Change >= 20 mmHg decrease	1	0	0	0
Pulse rate: <40 bpm	0	0	0	0
Pulse rate: >120 bpm	0	0	0	0

End point values	Cohort 2, Safety Extension Phase: Fesoterodine 4 mg	Cohort 1, Safety Extension Phase: Fesoterodine 8 mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	28	37		
Units: subjects				
SBP: <90 mmHg	2	3		
SBP: Change >= 30 mmHg increase	0	0		
SBP: Change >= 30 mmHg decrease	0	1		
DBP: <50 mmHg	0	2		
DBP: Change >= 20 mmHg increase	2	0		
DBP: Change >= 20 mmHg decrease	0	0		
Pulse rate: <40 bpm	0	0		
Pulse rate: >120 bpm	1	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Clinically Significant Urinary Tract Infections (UTI): Active Comparator/Efficacy Phase

End point title	Number of Subjects With Clinically Significant Urinary Tract Infections (UTI): Active Comparator/Efficacy Phase

End point description:

Clinically significant UTI, counted as an adverse event was defined as: positive urine culture with a uropathogen (defined as >=10^5 colony forming unit per milliliter [CFU/mL]) and the presence of symptoms, or pyuria (defined as >50 white blood cells [WBC] per high-pass filter [hpf]) and the presence of symptoms, or positive urine culture with a uropathogen (defined as >=10^5 CFU/mL) with or without symptoms in a subject with a documented history of vesicoureteral reflux (VUR). Safety analysis set population for active comparator phase and efficacy phase: all subject of respective cohorts

who received at least 1 dose of study medication in relevant phase of the study.

End point type	Secondary

End point timeframe:

Week 1 up to Week 12

End point values	Cohort 1, Active Comparator Phase: Fesoterodine 4 mg	Cohort 1, Active Comparator Phase: Fesoterodine 8 mg	Cohort 1, Active Comparator Phase: Oxybutynin	Cohort 2, Efficacy Phase: Fesoterodine 2 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42	42	40	28
Units: subjects	4	1	4	3

End point values	Cohort 2, Efficacy Phase: Fesoterodine 4 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	29			
Units: subjects	4			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Clinically Significant Urinary Tract Infections (UTI): Safety Extension Phase

End point title	Number of Subjects With Clinically Significant Urinary Tract Infections (UTI): Safety Extension Phase

End point description:

Clinically significant UTI, counted as an adverse event was defined as: positive urine culture with a uropathogen (defined as >=10^5 CFU/mL) and the presence of symptoms, or pyuria (defined as >50 WBC per hpf and the presence of symptoms, or positive urine culture with a uropathogen (defined as >=10^5 CFU/mL) with or without symptoms in a subject with a documented history of VUR. Safety analysis set population for safety extension phase included all subjects of respective cohorts who received at least 1 dose of study medication in the relevant phase of the study.

End point type	Secondary

End point timeframe:

Week 12 up to Week 26

End point values	Cohort 1, Safety Extension Phase: Fesoterodine 4 mg	Cohort 1, SEP: Oxybutynin Then Fesoterodine 4 mg	Cohort 1, SEP: Oxybutynin Then Fesoterodine 8 mg	Cohort 2, Safety Extension Phase: Fesoterodine 2 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	30	16	20	20
Units: subjects	0	2	0	1

End point values	Cohort 2, Safety Extension Phase: Fesoterodine 4 mg	Cohort 1, Safety Extension Phase: Fesoterodine 8 mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	28	37		
Units: subjects	5	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Clinical Laboratory Abnormalities: Active Comparator/Efficacy Phase

End point title	Number of Subjects With Clinical Laboratory Abnormalities: Active Comparator/Efficacy Phase

End point description:

Hemoglobin gram per deciliter (g/L) hematocrit, erythrocytes <0.8*lower limit of normal (LLN), platelets<0.5*LLN>1.75*upper limit of normal (ULN), leukocytes <0.6*LLN>1.5*ULN, lymphocytes, neutrophils, <0.8*LLN >1.2*ULN, basophils, eosinophils, monocytes monocytes/leukocytes >1.2*ULN; bilirubin, direct, bilirubin >1.5*ULN, aspartate aminotransferase (AT), alanine AT, gamma glutamyl transferase, lactate dehydrogenase, alkaline phosphatase>3.0*ULN, protein, albumin, pohosphate <0.8*LLN >1.2*ULN, blood urea nitrogen, creatinine >1.3*ULN, urate >1.2*ULN, sodium<0.95*LLN>1.05*ULN, potassium, chloride, calcium bicarbonate<0.9*LLN>1.1*ULN, glucose<0.6*LLN>1.5*ULN, creatine kinase >2.0*ULN, specific gravity <1.003>1.030, pH <4.5>8, urine glucose, ketones, urine protein, urine hemoglobin, urine bilirubin, nitrite, >=1, urine erythrocytes, urine leukocytes >=20, epithelial cells >=6, bacteria >20. Safety analysis set analysed. Here "N": subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Week 1 up to Week 12

End point values	Cohort 1, Active Comparator Phase: Fesoterodine 4 mg	Cohort 1, Active Comparator Phase: Fesoterodine 8 mg	Cohort 1, Active Comparator Phase: Oxybutynin	Cohort 2, Efficacy Phase: Fesoterodine 2 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	39	41	39	24
Units: subjects	30	29	27	19

End point values	Cohort 2, Efficacy Phase: Fesoterodine 4 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	29			
Units: subjects	19			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Clinical Laboratory Abnormalities: Safety Extension Phase

End point title	Number of Subjects With Clinical Laboratory Abnormalities: Safety Extension Phase

End point description:

Hemoglobin gram per deciliter (g/L) hematocrit, erythrocytes <0.8*lower limit of normal (LLN), platelets<0.5*LLN>1.75*upper limit of normal (ULN), leukocytes <0.6*LLN>1.5*ULN, lymphocytes, neutrophils, <0.8*LLN >1.2*ULN, basophils, eosinophils, monocytes monocytes/leukocytes >1.2*ULN; bilirubin, direct, bilirubin >1.5*ULN, aspartate aminotransferase (AT), alanine AT, gamma glutamyl transferase, lactate dehydrogenase, alkaline phosphatase>3.0*ULN, protein, albumin, pohosphate <0.8*LLN >1.2*ULN, blood urea nitrogen, creatinine >1.3*ULN, urate >1.2*ULN, sodium<0.95*LLN>1.05*ULN, potassium, chloride, calcium bicarbonate<0.9*LLN>1.1*ULN, glucose<0.6*LLN>1.5*ULN, creatine kinase >2.0*ULN, specific gravity <1.003>1.030, pH <4.5>8, urine glucose, ketones, urine protein, urine hemoglobin, urine bilirubin, nitrite, >=1, urine erythrocytes, urine leukocytes >=20, epithelial cells >=6, bacteria >20. Safety analysis set analysed. Here "N": subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Week 12 up to Week 26

End point values	Cohort 1, Safety Extension Phase: Fesoterodine 4 mg	Cohort 1, SEP: Oxybutynin Then Fesoterodine 4 mg	Cohort 1, SEP: Oxybutynin Then Fesoterodine 8 mg	Cohort 2, Safety Extension Phase: Fesoterodine 2 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	30	16	19	20
Units: subjects	19	7	12	15

End point values	Cohort 2, Safety Extension Phase: Fesoterodine 4 mg	Cohort 1, Safety Extension Phase: Fesoterodine 8 mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	28	36		
Units: subjects	21	22		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Post-Void Residual (PVR) Volume at Weeks 4, 12: Active Comparator Phase/Efficacy Phase

End point title	Change From Baseline in Post-Void Residual (PVR) Volume at Weeks 4, 12: Active Comparator Phase/Efficacy Phase

End point description:

PVR volume measurement was measured by an ultrasound. PVR volume was only assessed for subjects who did not perform clean intermittent catheterisation or in any subjects who had >1 UTI during the study. Safety analysis set population for active comparator phase and efficacy phase included all subjects of respective cohorts who received at least 1 dose of study medication in the relevant phase. Here "N": subjects evaluable for this endpoint and "n": subjects evaluable for this endpoint for time points.

End point type	Secondary

End point timeframe:

Baseline, Week 4, 12

End point values	Cohort 1, Active Comparator Phase: Fesoterodine 4 mg	Cohort 1, Active Comparator Phase: Fesoterodine 8 mg	Cohort 1, Active Comparator Phase: Oxybutynin	Cohort 2, Efficacy Phase: Fesoterodine 2 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	6	7	9	6
Units: mL				
arithmetic mean (standard deviation)				
Baseline (n=6, 7, 9, 6, 6)	7.00 (± 8.20)	9.57 (± 12.54)	5.78 (± 7.98)	14.7 (± 14.31)
Change at Week 4 (n=5, 6, 9, 3, 4)	5.40 (± 7.60)	-7.33 (± 10.88)	19.11 (± 24.52)	-2.00 (± 6.24)
Change at Week 12 (n=5, 6 7, 4, 4)	25.60 (± 53.42)	-4.00 (± 8.41)	12.86 (± 43.48)	2.50 (± 16.05)

End point values	Cohort 2, Efficacy Phase: Fesoterodine 4 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	6			
Units: mL				
arithmetic mean (standard deviation)				
Baseline (n=6, 7, 9, 6, 6)	10.7 (± 7.94)			
Change at Week 4 (n=5, 6, 9, 3, 4)	10.25 (± 34.40)			
Change at Week 12 (n=5, 6 7, 4, 4)	0.75 (± 17.46)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Post-Void Residual Volume at Week 24: Safety Extension Phase

End point title	Change From Baseline in Post-Void Residual Volume at Week 24: Safety Extension Phase

End point description:

PVR volume measurement was measured by an ultrasound. PVR volume was only assessed for subjects who did not perform clean intermittent catheterisation or in any subjects who had >1 UTI during the study. Safety analysis set population for safety extension phase: all subjects of respective cohorts who received at least 1 dose of study medication in the relevant phase. Here "N": subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	Cohort 1, Safety Extension Phase: Fesoterodine 4 mg	Cohort 1, SEP: Oxybutynin Then Fesoterodine 4 mg	Cohort 1, SEP: Oxybutynin Then Fesoterodine 8 mg	Cohort 2, Safety Extension Phase: Fesoterodine 2 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	5	3	3
Units: mL				
arithmetic mean (standard deviation)	11.50 (± 23.67)	18.00 (± 31.36)	36.67 (± 59.23)	21.67 (± 20.21)

End point values	Cohort 2, Safety Extension Phase: Fesoterodine 4 mg	Cohort 1, Safety Extension Phase: Fesoterodine 8 mg		
Subject group type	Subject analysis set	Subject analysis set		

Number of subjects analysed	4	5		
Units: mL				
arithmetic mean (standard deviation)	2.75 (± 14.50)	11.60 (± 29.43)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Clinically Relevant Changes in Physical Examination Findings From Baseline to Week 12: Active Comparator/Efficacy Phase

End point title	Number of Subjects With Clinically Relevant Changes in Physical Examination Findings From Baseline to Week 12: Active Comparator/Efficacy Phase

End point description:

Physical examination included assessment of the general appearance and the skin, head, ears, eyes, nose, mouth, throat, respiratory, cardiovascular, gastrointestinal, musculoskeletal and neurological systems. Clinically relevant changes in physical findings were assessed by the investigator. Safety analysis set population for active comparator phase and efficacy phase: all subjects of respective cohorts who received at least 1 dose of study medication in relevant phase of the study. Here "N": subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline up to Week 12

End point values	Cohort 1, Active Comparator Phase: Fesoterodine 4 mg	Cohort 1, Active Comparator Phase: Fesoterodine 8 mg	Cohort 1, Active Comparator Phase: Oxybutynin	Cohort 2, Efficacy Phase: Fesoterodine 2 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	38	42	40	28
Units: subjects	2	1	1	1

End point values	Cohort 2, Efficacy Phase: Fesoterodine 4 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	29			
Units: subjects	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Clinically Relevant Changes in Physical Examination Findings From Baseline to Week 24: Safety Extension Phase

End point title	Number of Subjects With Clinically Relevant Changes in Physical Examination Findings From Baseline to Week 24: Safety Extension Phase

End point description:

Physical examination included assessment of the general appearance and the skin, head, ears, eyes, nose, mouth, throat, respiratory, cardiovascular, gastrointestinal, musculoskeletal and neurological systems. Clinically relevant changes in physical findings were assessed by the investigator. Safety analysis set population for safety extension phase included all subjects of respective cohorts who received at least 1 dose of study medication in the relevant phase of the study.

End point type	Secondary

End point timeframe:

Baseline up to Week 24

End point values	Cohort 1, Safety Extension Phase: Fesoterodine 4 mg	Cohort 1, SEP: Oxybutynin Then Fesoterodine 4 mg	Cohort 1, SEP: Oxybutynin Then Fesoterodine 8 mg	Cohort 2, Safety Extension Phase: Fesoterodine 2 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	30	16	20	20
Units: subjects	3	0	0	0

End point values	Cohort 2, Safety Extension Phase: Fesoterodine 4 mg	Cohort 1, Safety Extension Phase: Fesoterodine 8 mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	28	37		
Units: subjects	2	2		

Statistical analyses

No statistical analyses for this end point

Secondary: Absorption Rate Constant (Ka) of Fesoterodine

End point title	Absorption Rate Constant (Ka) of Fesoterodine

End point description:

Absorption rate constant is used to determine rate at which drug is entering into body. Pharmacokinetic (PK) analysis was not done separately for each dose of fesoterodine in respective cohorts and were combined for PK analysis using PK modelling approach. The PK analysis population included all subjects randomised and treated with fesoterodine and who had at least 1 of the PK parameters of primary interest during the study.

End point type	Secondary

End point timeframe:

Week 4, Day 1: pre-dose (when dose administered at clinic) or if dose taken at home up to 3 hours before coming to the clinic- sampling just after arrival at clinic, 5 hours post-dose, 8-10 hours post-dose (if subjects remained at clinic)

End point values	Fesoterodine Pooled			
Subject group type	Subject analysis set			
Number of subjects analysed	121			
Units: liter per hour				
arithmetic mean (standard error)	0.0897 (± 5.99)			

Statistical analyses

No statistical analyses for this end point

Secondary: Apparent Oral Clearance (CL/F) of Fesoterodine

End point title	Apparent Oral Clearance (CL/F) of Fesoterodine

End point description:

Clearance determines the rate at which a drug is metabolized or eliminated by normal biological processes. PK analysis was not done separately for each dose of fesoterodine in respective cohorts and were combined for PK analysis using PK modelling approach. The PK analysis population included all subjects randomised and treated with fesoterodine and who had at least 1 of the PK parameters of primary interest during the study.

End point type	Secondary

End point timeframe:

Week 4, Day 1: pre-dose (when dose administered at clinic) or if dose taken at home up to 3 hours before coming to the clinic- sampling just after arrival at clinic, 5 hours post-dose, 8-10 hours post-dose (if subjects remained at clinic)

End point values	Fesoterodine Pooled			
Subject group type	Subject analysis set			
Number of subjects analysed	121			
Units: liter per hour				
arithmetic mean (standard error)	71.6 (± 6.7)			

Statistical analyses

No statistical analyses for this end point

Secondary: Volume of Distribution (Vd) of Fesoterodine

End point title	Volume of Distribution (Vd) of Fesoterodine

End point description:

Volume of distribution is defined as the theoretical volume in which the total amount of drug would need to be uniformly distributed to produce the desired plasma concentration of a drug. PK analysis was not done separately for each dose of fesoterodine in respective cohorts and were combined for PK analysis using PK modelling approach. The PK analysis population included all subjects randomised and treated with fesoterodine and who had at least 1 of the PK parameters of primary interest during the study.

End point type	Secondary

End point timeframe:

Week 4, Day 1: pre-dose (when dose administered at clinic) or if dose taken at home up to 3 hours before coming to the clinic- sampling just after arrival at clinic, 5 hours post-dose, 8-10 hours post-dose (if subjects remained at clinic)

End point values	Fesoterodine Pooled			
Subject group type	Subject analysis set			
Number of subjects analysed	121			
Units: liter				
arithmetic mean (standard error)	68.1 (± 29.7)			

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Baseline up to Week 26

Adverse event reporting additional description:

Same event may appear as AE and serious AE, what is presented are distinct events. Event may be categorized as serious in 1 subject and as non-serious in another subject or 1 subject may have experienced both serious and non-serious event during study. Safety analysis population.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22.1

Reporting groups

Reporting group title	Cohort 1, Active Comparator Phase: Fesoterodine 8 mg

Reporting group description:

Subjects with body weight >25 kg were randomised to receive fesoterodine 4 mg PR tablets orally once daily for first 1 week and if dose was tolerated well, then subjects received 8 mg PR tablet orally once daily for next 11 weeks in active comparator phase.

Reporting group title	Cohort 1, Active Comparator Phase: Fesoterodine 4 mg

Reporting group description:

Subjects with body weight >25 kg were randomised to receive fesoterodine 4 mg PR tablet orally once daily for 12 weeks in active comparator phase.

Reporting group title	Cohort 1, Safety Extension Phase: Fesoterodine 4 mg

Reporting group description:

Subjects with body weight >25 kg received fesoterodine 4 mg PR tablet orally once daily for 12 weeks in safety extension phase.

Reporting group title	Cohort 1, Active Comparator Phase: Oxybutynin

Reporting group description:

Subjects with body weight >25 kg were randomised to receive oxybutynin ER tablet, at a daily dose in accordance with approved pediatric labeling and accepted practice. Dose titration was done for first 4 weeks. After Week 4, subjects remained on the optimised daily dose for next 8 weeks, in active comparator phase.

Reporting group title	Cohort 1, Safety Extension Phase (SEP): Fesoterodine 8 mg

Reporting group description:

Subjects with body weight >25 kg received fesoterodine 8 mg PR tablet orally once daily for 12 weeks in safety extension phase.

Reporting group title	Cohort 1, SEP: Oxybutynin Then Fesoterodine 4 mg

Reporting group description:

Subjects with body weight >25 kg who were randomised to receive oxybutynin ER tablet, at a daily dose in accordance with approved pediatric labeling and accepted practice, in active comparator phase; were allocated by investigator to receive fesoterodine 4 mg PR tablet orally once daily for 12 weeks in the safety extension phase.

Reporting group title	Cohort 1, SEP: Oxybutynin Then Fesoterodine 8 mg

Reporting group description:

Subjects with body weight >25 kg who were randomised to receive oxybutynin ER tablet, at a daily dose in accordance with approved pediatric labeling and accepted practice, in active comparator phase; were allocated by investigator to receive fesoterodine 4 mg PR tablet orally once daily for first 1 week followed by fesoterodine 8 mg PR tablet orally once daily for another 11 weeks (if the fesoterodine 4 mg dose was well tolerated) in the safety extension phase.

Reporting group title	Cohort 2 Efficacy Phase: Fesoterodine 4 mg

Reporting group description:

Subjects with body weight <=25 kg were randomised to receive fesoterodine 2 mg BIC capsule orally once daily for first 1 week and if dose was tolerated well, then subjects received 4 mg BIC capsule orally once daily for next 11 weeks in efficacy phase.

Reporting group title	Cohort 2, Efficacy Phase: Fesoterodine 2 mg

Reporting group description:

Subjects with body weight <=25 kg were randomised to receive fesoterodine 2 mg BIC capsule orally once daily for 12 weeks in efficacy phase.

Reporting group title	Cohort 2, Safety Extension Phase: Fesoterodine 2 mg

Reporting group description:

Subjects with body weight <=25 kg received fesoterodine 2 mg BIC capsules orally once daily for 12 weeks in safety extension phase.

Reporting group title	Cohort 2, Safety Extension Phase: Fesoterodine 4 mg

Reporting group description:

Subjects with body weight <=25 kg received fesoterodine 4 mg BIC capsules orally once daily for 12 weeks in safety extension phase.

Serious adverse events	Cohort 1, Active Comparator Phase: Fesoterodine 8 mg	Cohort 1, Active Comparator Phase: Fesoterodine 4 mg	Cohort 1, Safety Extension Phase: Fesoterodine 4 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 42 (4.76%)	3 / 42 (7.14%)	0 / 30 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			

Decubitus ulcer			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Epiphysiolysis			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complicated appendicitis			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epididymitis			
subjects affected / exposed	1 / 42 (2.38%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Viral infection			
subjects affected / exposed	1 / 42 (2.38%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dengue fever			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Cohort 1, Active Comparator Phase: Oxybutynin	Cohort 1, Safety Extension Phase (SEP): Fesoterodine 8 mg	Cohort 1, SEP: Oxybutynin Then Fesoterodine 4 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 40 (2.50%)	2 / 37 (5.41%)	0 / 16 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 40 (0.00%)	1 / 37 (2.70%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 40 (2.50%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			

subjects affected / exposed	1 / 40 (2.50%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Decubitus ulcer			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Epiphysiolysis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complicated appendicitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epididymitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	0 / 40 (0.00%)	1 / 37 (2.70%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Urinary tract infection			
subjects affected / exposed	1 / 40 (2.50%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dengue fever			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Cohort 1, SEP: Oxybutynin Then Fesoterodine 8 mg	Cohort 2 Efficacy Phase: Fesoterodine 4 mg	Cohort 2, Efficacy Phase: Fesoterodine 2 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 20 (0.00%)	2 / 29 (6.90%)	2 / 28 (7.14%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	1 / 28 (3.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			

subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Decubitus ulcer			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Epiphysiolysis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complicated appendicitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epididymitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 20 (0.00%)	1 / 29 (3.45%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pyelonephritis acute			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 20 (0.00%)	1 / 29 (3.45%)	1 / 28 (3.57%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 20 (0.00%)	1 / 29 (3.45%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dengue fever			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Cohort 2, Safety Extension Phase: Fesoterodine 2 mg	Cohort 2, Safety Extension Phase: Fesoterodine 4 mg	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 20 (0.00%)	2 / 28 (7.14%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	

occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydronephrosis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Decubitus ulcer			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Epiphysiolysis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Complicated appendicitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epididymitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Peritonitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis acute			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	0 / 20 (0.00%)	1 / 28 (3.57%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dengue fever			
subjects affected / exposed	0 / 20 (0.00%)	1 / 28 (3.57%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Cohort 1, Active Comparator Phase: Fesoterodine 8 mg	Cohort 1, Active Comparator Phase: Fesoterodine 4 mg	Cohort 1, Safety Extension Phase: Fesoterodine 4 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	19 / 42 (45.24%)	26 / 42 (61.90%)	14 / 30 (46.67%)
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin papilloma			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Social circumstances			
Wheelchair user			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Catheter site pain			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	1 / 30 (3.33%)
occurrences (all)	0	1	1
Malaise			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Mass			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 42 (2.38%)	2 / 42 (4.76%)	1 / 30 (3.33%)
occurrences (all)	1	3	2
Adverse drug reaction			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 30 (0.00%)
occurrences (all)	0	1	0

Feeling cold			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	1 / 42 (2.38%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Thirst			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Temperature intolerance			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Aggression			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Behaviour disorder			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Encopresis			
subjects affected / exposed	1 / 42 (2.38%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Restlessness			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			
Genital pain			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Menstruation irregular			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			

Skin laceration			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Investigations			
Bacterial test positive			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Blood glucose decreased			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Eosinophil count increased			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Heart rate increased			
subjects affected / exposed	1 / 42 (2.38%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Investigation abnormal			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Residual urine volume increased			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Urine analysis abnormal			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 42 (0.00%)	2 / 42 (4.76%)	0 / 30 (0.00%)
occurrences (all)	0	2	0
Urine output increased			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
White blood cells urine positive			
subjects affected / exposed	1 / 42 (2.38%)	0 / 42 (0.00%)	0 / 30 (0.00%)

occurrences (all)	1	0	0
Cystogram			
subjects affected / exposed	1 / 42 (2.38%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Supraventricular extrasystoles			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	2 / 42 (4.76%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	2	0	0
Dyspnoea			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	1 / 42 (2.38%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Nasal obstruction			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 42 (2.38%)	0 / 42 (0.00%)	1 / 30 (3.33%)
occurrences (all)	2	0	1
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 30 (0.00%)

occurrences (all)	0	1	0
Respiratory disorder			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Dry throat			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Rhinitis allergic			
subjects affected / exposed	1 / 42 (2.38%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Rhinorrhoea			
subjects affected / exposed	1 / 42 (2.38%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Nasal congestion			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	3 / 42 (7.14%)	2 / 42 (4.76%)	1 / 30 (3.33%)
occurrences (all)	3	2	1
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
Cognitive disorder			
subjects affected / exposed	1 / 42 (2.38%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Syncope			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Astigmatism			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0

Myopia			
subjects affected / exposed	1 / 42 (2.38%)	1 / 42 (2.38%)	1 / 30 (3.33%)
occurrences (all)	1	1	1
Strabismus			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
Accommodation disorder			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Eye pruritus			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Vertigo positional			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 42 (2.38%)	1 / 42 (2.38%)	0 / 30 (0.00%)
occurrences (all)	1	1	0
Abdominal pain upper			
subjects affected / exposed	1 / 42 (2.38%)	2 / 42 (4.76%)	0 / 30 (0.00%)
occurrences (all)	1	2	0
Constipation			
subjects affected / exposed	3 / 42 (7.14%)	3 / 42 (7.14%)	0 / 30 (0.00%)
occurrences (all)	3	3	0
Diarrhoea			
subjects affected / exposed	3 / 42 (7.14%)	5 / 42 (11.90%)	1 / 30 (3.33%)

occurrences (all)	4	7	1
Dry mouth			
subjects affected / exposed	4 / 42 (9.52%)	3 / 42 (7.14%)	1 / 30 (3.33%)
occurrences (all)	4	3	1
Faeces soft			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Lip dry			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 42 (2.38%)	2 / 42 (4.76%)	0 / 30 (0.00%)
occurrences (all)	2	2	0
Vomiting			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	1 / 30 (3.33%)
occurrences (all)	0	1	1
Abdominal discomfort			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Dental caries			
subjects affected / exposed	1 / 42 (2.38%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Dysphagia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Enteritis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 30 (0.00%)

occurrences (all)	0	1	0
Lip erythema			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
Hypertonic bladder			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Incontinence			
subjects affected / exposed	2 / 42 (4.76%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	2	0	0
Pollakiuria			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Renal failure			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Urine odour abnormal			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Urethral pain			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Urinary tract disorder			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Urine flow decreased			

subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Decubitus ulcer			
subjects affected / exposed	1 / 42 (2.38%)	2 / 42 (4.76%)	1 / 30 (3.33%)
occurrences (all)	1	3	1
Dermal cyst			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Dermatitis atopic			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Skin odour abnormal			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 30 (0.00%)
occurrences (all)	0	1	0

Rash macular			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	1 / 42 (2.38%)	0 / 42 (0.00%)	1 / 30 (3.33%)
occurrences (all)	1	0	1
Spinal deformity			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Synovitis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Arthritis			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 30 (0.00%)
occurrences (all)	0	2	0
Joint contracture			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	1 / 42 (2.38%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Neck pain			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Dehydration			

subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Polydipsia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Asymptomatic bacteriuria			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Bacteriuria			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis bacterial			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	1 / 42 (2.38%)	1 / 42 (2.38%)	0 / 30 (0.00%)
occurrences (all)	2	1	0
Gastroenteritis viral			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Infection parasitic			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	1 / 42 (2.38%)	4 / 42 (9.52%)	0 / 30 (0.00%)
occurrences (all)	1	5	0

Mastitis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 42 (2.38%)	5 / 42 (11.90%)	1 / 30 (3.33%)
occurrences (all)	1	6	1
Oral herpes			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
Pyelonephritis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Sinusitis			
subjects affected / exposed	1 / 42 (2.38%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Tonsillitis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 42 (2.38%)	1 / 42 (2.38%)	0 / 30 (0.00%)
occurrences (all)	2	1	0
Urinary tract infection			
subjects affected / exposed	1 / 42 (2.38%)	3 / 42 (7.14%)	0 / 30 (0.00%)
occurrences (all)	1	4	0
Varicella			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 42 (0.00%)	4 / 42 (9.52%)	0 / 30 (0.00%)
occurrences (all)	0	4	0

Dermatitis infected			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
Ear lobe infection			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
Bronchitis			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Cellulitis			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Conjunctivitis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	1 / 42 (2.38%)	1 / 42 (2.38%)	0 / 30 (0.00%)
occurrences (all)	1	1	0
Cystitis bacterial			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Device related infection			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Folliculitis			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Fungal skin infection			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Hordeolum			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 30 (0.00%)
occurrences (all)	0	1	0

Paronychia			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Pharyngotonsillitis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Scrotal infection			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	1 / 42 (2.38%)	0 / 42 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	Cohort 1, Active Comparator Phase: Oxybutynin	Cohort 1, Safety Extension Phase (SEP): Fesoterodine 8 mg	Cohort 1, SEP: Oxybutynin Then Fesoterodine 4 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	30 / 40 (75.00%)	13 / 37 (35.14%)	9 / 16 (56.25%)
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin papilloma			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Social circumstances			
Wheelchair user			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Catheter site pain			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

Fatigue			
subjects affected / exposed	1 / 40 (2.50%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Malaise			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Mass			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Non-cardiac chest pain			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 40 (2.50%)	1 / 37 (2.70%)	2 / 16 (12.50%)
occurrences (all)	1	1	2
Adverse drug reaction			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Feeling cold			
subjects affected / exposed	1 / 40 (2.50%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Oedema peripheral			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Thirst			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Temperature intolerance			
subjects affected / exposed	0 / 40 (0.00%)	1 / 37 (2.70%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Aggression			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Anxiety			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)

occurrences (all)	0	0	0
Behaviour disorder			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Encopresis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Restlessness			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Genital pain			
subjects affected / exposed	1 / 40 (2.50%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Menstruation irregular			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Skin laceration			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Investigations			
Bacterial test positive			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Blood glucose decreased			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Eosinophil count increased			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Heart rate increased			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)

occurrences (all)	0	0	0
Investigation abnormal			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Residual urine volume increased			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Urine analysis abnormal			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	1 / 40 (2.50%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Urine output increased			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
White blood cells urine positive			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Cystogram			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Supraventricular extrasystoles			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			

Asthma			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 40 (0.00%)	1 / 37 (2.70%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Dyspnoea			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	1 / 40 (2.50%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Nasal obstruction			
subjects affected / exposed	1 / 40 (2.50%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 40 (0.00%)	1 / 37 (2.70%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract inflammation			
subjects affected / exposed	1 / 40 (2.50%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Respiratory disorder			
subjects affected / exposed	1 / 40 (2.50%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Dry throat			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 40 (0.00%)	1 / 37 (2.70%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Rhinorrhoea			
subjects affected / exposed	0 / 40 (0.00%)	1 / 37 (2.70%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Nasal congestion			
subjects affected / exposed	0 / 40 (0.00%)	1 / 37 (2.70%)	0 / 16 (0.00%)
occurrences (all)	0	1	0

Nervous system disorders			
Dizziness			
subjects affected / exposed	1 / 40 (2.50%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Headache			
subjects affected / exposed	5 / 40 (12.50%)	3 / 37 (8.11%)	1 / 16 (6.25%)
occurrences (all)	5	4	1
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Astigmatism			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Myopia			
subjects affected / exposed	1 / 40 (2.50%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	2	0	0
Strabismus			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Accommodation disorder			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	1 / 40 (2.50%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Visual impairment			
subjects affected / exposed	0 / 40 (0.00%)	1 / 37 (2.70%)	0 / 16 (0.00%)

occurrences (all)	0	1	0

Ear and labyrinth disorders			
Vertigo positional			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	2 / 40 (5.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	2	0	0
Abdominal pain upper			
subjects affected / exposed	2 / 40 (5.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	2	0	0
Constipation			
subjects affected / exposed	5 / 40 (12.50%)	0 / 37 (0.00%)	1 / 16 (6.25%)
occurrences (all)	5	0	1
Diarrhoea			
subjects affected / exposed	1 / 40 (2.50%)	1 / 37 (2.70%)	0 / 16 (0.00%)
occurrences (all)	1	1	0
Dry mouth			
subjects affected / exposed	11 / 40 (27.50%)	0 / 37 (0.00%)	1 / 16 (6.25%)
occurrences (all)	12	0	1
Faeces soft			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Lip dry			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	2 / 40 (5.00%)	1 / 37 (2.70%)	0 / 16 (0.00%)
occurrences (all)	2	1	0
Vomiting			
subjects affected / exposed	2 / 40 (5.00%)	1 / 37 (2.70%)	1 / 16 (6.25%)

occurrences (all)	2	1	1
Toothache			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Abdominal discomfort			
subjects affected / exposed	1 / 40 (2.50%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Abdominal pain lower			
subjects affected / exposed	1 / 40 (2.50%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Dental caries			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	1 / 40 (2.50%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Enteritis			
subjects affected / exposed	1 / 40 (2.50%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Flatulence			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Lip erythema			
subjects affected / exposed	1 / 40 (2.50%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Stomatitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	1 / 40 (2.50%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Hypertonic bladder			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Incontinence			

subjects affected / exposed	0 / 40 (0.00%)	1 / 37 (2.70%)	0 / 16 (0.00%)
occurrences (all)	0	2	0
Pollakiuria			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Renal failure			
subjects affected / exposed	1 / 40 (2.50%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Urinary incontinence			
subjects affected / exposed	4 / 40 (10.00%)	0 / 37 (0.00%)	1 / 16 (6.25%)
occurrences (all)	4	0	1
Urine odour abnormal			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Urethral pain			
subjects affected / exposed	1 / 40 (2.50%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Urinary tract disorder			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Urine flow decreased			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	1 / 40 (2.50%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Decubitus ulcer			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Dermal cyst			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	1 / 40 (2.50%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0

Dermatitis atopic			
subjects affected / exposed	1 / 40 (2.50%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Eczema			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	1 / 40 (2.50%)	1 / 37 (2.70%)	0 / 16 (0.00%)
occurrences (all)	1	1	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Skin odour abnormal			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	1 / 40 (2.50%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 40 (0.00%)	1 / 37 (2.70%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Spinal deformity			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)

occurrences (all)	0	0	0
Synovitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Arthritis			
subjects affected / exposed	1 / 40 (2.50%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Joint contracture			
subjects affected / exposed	1 / 40 (2.50%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Muscular weakness			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 40 (2.50%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Dehydration			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Polydipsia			
subjects affected / exposed	1 / 40 (2.50%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Asymptomatic bacteriuria			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Bacteriuria			
subjects affected / exposed	1 / 40 (2.50%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Conjunctivitis bacterial			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

Escherichia urinary tract infection			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 40 (0.00%)	2 / 37 (5.41%)	0 / 16 (0.00%)
occurrences (all)	0	2	0
Gastroenteritis viral			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Infection parasitic			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	1 / 40 (2.50%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Mastitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	2 / 40 (5.00%)	2 / 37 (5.41%)	1 / 16 (6.25%)
occurrences (all)	2	2	2
Oral herpes			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	1 / 40 (2.50%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Pyelonephritis			
subjects affected / exposed	2 / 40 (5.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	2	0	0

Rhinitis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 37 (2.70%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Sinusitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 40 (2.50%)	1 / 37 (2.70%)	1 / 16 (6.25%)
occurrences (all)	1	1	2
Urinary tract infection			
subjects affected / exposed	3 / 40 (7.50%)	1 / 37 (2.70%)	2 / 16 (12.50%)
occurrences (all)	5	2	3
Varicella			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Dermatitis infected			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Ear lobe infection			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	1 / 40 (2.50%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0

Cystitis			
subjects affected / exposed	1 / 40 (2.50%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Cystitis bacterial			
subjects affected / exposed	1 / 40 (2.50%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Device related infection			
subjects affected / exposed	1 / 40 (2.50%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Ear infection			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Pharyngotonsillitis			
subjects affected / exposed	1 / 40 (2.50%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Scrotal infection			
subjects affected / exposed	1 / 40 (2.50%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Eye infection			
subjects affected / exposed	0 / 40 (0.00%)	0 / 37 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Cohort 1, SEP: Oxybutynin Then Fesoterodine 8 mg	Cohort 2 Efficacy Phase: Fesoterodine 4 mg	Cohort 2, Efficacy Phase: Fesoterodine 2 mg
Total subjects affected by non-serious			

adverse events			
subjects affected / exposed	11 / 20 (55.00%)	17 / 29 (58.62%)	19 / 28 (67.86%)
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin papilloma			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Social circumstances			
Wheelchair user			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Catheter site pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Mass			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	1 / 20 (5.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	1	0	0
Pyrexia			
subjects affected / exposed	0 / 20 (0.00%)	2 / 29 (6.90%)	1 / 28 (3.57%)
occurrences (all)	0	3	1

Adverse drug reaction			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Feeling cold			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Thirst			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Temperature intolerance			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Aggression			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	1 / 20 (5.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	1	0	0
Behaviour disorder			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	1 / 28 (3.57%)
occurrences (all)	0	0	1
Encopresis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Restlessness			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Genital pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Menstruation irregular			

subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Skin laceration			
subjects affected / exposed	0 / 20 (0.00%)	1 / 29 (3.45%)	0 / 28 (0.00%)
occurrences (all)	0	1	0
Contusion			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Investigations			
Bacterial test positive			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	1 / 28 (3.57%)
occurrences (all)	0	0	1
Blood glucose decreased			
subjects affected / exposed	1 / 20 (5.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	1	0	0
Eosinophil count increased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	1 / 28 (3.57%)
occurrences (all)	0	0	1
Heart rate increased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Investigation abnormal			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	1 / 28 (3.57%)
occurrences (all)	0	0	1
Residual urine volume increased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	1 / 28 (3.57%)
occurrences (all)	0	0	1
Urine analysis abnormal			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Urine output increased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)

occurrences (all)	0	0	0
White blood cells urine positive			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Cystogram			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Supraventricular extrasystoles			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	1 / 28 (3.57%)
occurrences (all)	0	0	1
Tachycardia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	1 / 28 (3.57%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	1 / 28 (3.57%)
occurrences (all)	0	0	1
Cough			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	1 / 28 (3.57%)
occurrences (all)	0	0	1
Dyspnoea			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	1 / 28 (3.57%)
occurrences (all)	0	0	3
Epistaxis			
subjects affected / exposed	1 / 20 (5.00%)	2 / 29 (6.90%)	0 / 28 (0.00%)
occurrences (all)	1	2	0
Nasal obstruction			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)

occurrences (all)	0	0	0
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	1 / 28 (3.57%)
occurrences (all)	0	0	1
Respiratory disorder			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Dry throat			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	2 / 28 (7.14%)
occurrences (all)	0	0	4
Headache			
subjects affected / exposed	1 / 20 (5.00%)	2 / 29 (6.90%)	0 / 28 (0.00%)
occurrences (all)	1	2	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Eye disorders			

Astigmatism			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	1 / 28 (3.57%)
occurrences (all)	0	0	1
Myopia			
subjects affected / exposed	1 / 20 (5.00%)	1 / 29 (3.45%)	0 / 28 (0.00%)
occurrences (all)	1	1	0
Strabismus			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	1 / 28 (3.57%)
occurrences (all)	0	0	1
Vision blurred			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Accommodation disorder			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Vertigo positional			
subjects affected / exposed	1 / 20 (5.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	1	0	0
Ear pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 20 (0.00%)	1 / 29 (3.45%)	1 / 28 (3.57%)
occurrences (all)	0	1	1
Abdominal pain upper			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 20 (0.00%)	2 / 29 (6.90%)	0 / 28 (0.00%)

occurrences (all)	0	2	0
Diarrhoea			
subjects affected / exposed	0 / 20 (0.00%)	1 / 29 (3.45%)	1 / 28 (3.57%)
occurrences (all)	0	1	1
Dry mouth			
subjects affected / exposed	0 / 20 (0.00%)	1 / 29 (3.45%)	0 / 28 (0.00%)
occurrences (all)	0	1	0
Faeces soft			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	1 / 28 (3.57%)
occurrences (all)	0	0	1
Lip dry			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	1 / 28 (3.57%)
occurrences (all)	0	0	1
Nausea			
subjects affected / exposed	0 / 20 (0.00%)	1 / 29 (3.45%)	1 / 28 (3.57%)
occurrences (all)	0	1	1
Vomiting			
subjects affected / exposed	0 / 20 (0.00%)	1 / 29 (3.45%)	0 / 28 (0.00%)
occurrences (all)	0	1	0
Toothache			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Abdominal discomfort			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Dental caries			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Enteritis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)

occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Lip erythema			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Hypertonic bladder			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	1 / 28 (3.57%)
occurrences (all)	0	0	1
Incontinence			
subjects affected / exposed	1 / 20 (5.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	1	0	0
Pollakiuria			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 20 (0.00%)	2 / 29 (6.90%)	0 / 28 (0.00%)
occurrences (all)	0	3	0
Urine odour abnormal			
subjects affected / exposed	0 / 20 (0.00%)	1 / 29 (3.45%)	0 / 28 (0.00%)
occurrences (all)	0	1	0
Urethral pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Urinary tract disorder			

subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Urine flow decreased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Decubitus ulcer			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	1 / 28 (3.57%)
occurrences (all)	0	0	1
Dermal cyst			
subjects affected / exposed	0 / 20 (0.00%)	1 / 29 (3.45%)	0 / 28 (0.00%)
occurrences (all)	0	1	0
Dermatitis acneiform			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Dermatitis atopic			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	1 / 28 (3.57%)
occurrences (all)	0	0	1
Pruritus			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Skin odour abnormal			
subjects affected / exposed	0 / 20 (0.00%)	1 / 29 (3.45%)	0 / 28 (0.00%)
occurrences (all)	0	1	0
Urticaria			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0

Dermatitis allergic			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 20 (0.00%)	1 / 29 (3.45%)	0 / 28 (0.00%)
occurrences (all)	0	1	0
Pain in extremity			
subjects affected / exposed	1 / 20 (5.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	1	0	0
Spinal deformity			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	1 / 28 (3.57%)
occurrences (all)	0	0	1
Synovitis			
subjects affected / exposed	0 / 20 (0.00%)	1 / 29 (3.45%)	0 / 28 (0.00%)
occurrences (all)	0	1	0
Arthritis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Joint contracture			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			

Decreased appetite			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Dehydration			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Polydipsia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Asymptomatic bacteriuria			
subjects affected / exposed	0 / 20 (0.00%)	2 / 29 (6.90%)	4 / 28 (14.29%)
occurrences (all)	0	2	4
Bacteriuria			
subjects affected / exposed	1 / 20 (5.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	1	0	0
Conjunctivitis bacterial			
subjects affected / exposed	0 / 20 (0.00%)	1 / 29 (3.45%)	0 / 28 (0.00%)
occurrences (all)	0	2	0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 20 (0.00%)	1 / 29 (3.45%)	0 / 28 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	1 / 28 (3.57%)
occurrences (all)	0	0	1
Gastroenteritis viral			
subjects affected / exposed	1 / 20 (5.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	1	0	0
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	1 / 28 (3.57%)
occurrences (all)	0	0	1
Infection parasitic			
subjects affected / exposed	0 / 20 (0.00%)	1 / 29 (3.45%)	0 / 28 (0.00%)

occurrences (all)	0	1	0
Influenza			
subjects affected / exposed	1 / 20 (5.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	1	0	0
Mastitis			
subjects affected / exposed	1 / 20 (5.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	2 / 20 (10.00%)	3 / 29 (10.34%)	3 / 28 (10.71%)
occurrences (all)	2	3	3
Oral herpes			
subjects affected / exposed	0 / 20 (0.00%)	1 / 29 (3.45%)	0 / 28 (0.00%)
occurrences (all)	0	1	0
Pharyngitis			
subjects affected / exposed	0 / 20 (0.00%)	1 / 29 (3.45%)	0 / 28 (0.00%)
occurrences (all)	0	1	0
Pyelonephritis			
subjects affected / exposed	1 / 20 (5.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	2	0	0
Rhinitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	1 / 28 (3.57%)
occurrences (all)	0	0	1
Tonsillitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	1 / 28 (3.57%)
occurrences (all)	0	0	1
Upper respiratory tract infection			
subjects affected / exposed	0 / 20 (0.00%)	1 / 29 (3.45%)	0 / 28 (0.00%)
occurrences (all)	0	1	0
Urinary tract infection			
subjects affected / exposed	0 / 20 (0.00%)	3 / 29 (10.34%)	2 / 28 (7.14%)
occurrences (all)	0	4	7
Varicella			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)

occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Dermatitis infected			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Ear lobe infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Cystitis bacterial			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Device related infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)

occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Pharyngotonsillitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Scrotal infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 29 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Cohort 2, Safety Extension Phase: Fesoterodine 2 mg	Cohort 2, Safety Extension Phase: Fesoterodine 4 mg	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	11 / 20 (55.00%)	14 / 28 (50.00%)	
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin papilloma			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 20 (0.00%)	1 / 28 (3.57%)	
occurrences (all)	0	1	
Social circumstances			
Wheelchair user			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	

General disorders and administration site conditions			
Catheter site pain			
subjects affected / exposed	1 / 20 (5.00%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Fatigue			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Malaise			
subjects affected / exposed	0 / 20 (0.00%)	1 / 28 (3.57%)	
occurrences (all)	0	1	
Mass			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Non-cardiac chest pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Pyrexia			
subjects affected / exposed	2 / 20 (10.00%)	1 / 28 (3.57%)	
occurrences (all)	3	1	
Adverse drug reaction			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Feeling cold			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Oedema peripheral			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Thirst			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Temperature intolerance			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			

Aggression			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Anxiety			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Behaviour disorder			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Encopresis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Restlessness			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Reproductive system and breast disorders			
Genital pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Menstruation irregular			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Injury, poisoning and procedural complications			
Skin laceration			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Contusion			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Investigations			
Bacterial test positive			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Blood glucose decreased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	

Eosinophil count increased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Heart rate increased			
subjects affected / exposed	0 / 20 (0.00%)	1 / 28 (3.57%)	
occurrences (all)	0	1	
Investigation abnormal			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Residual urine volume increased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Urine analysis abnormal			
subjects affected / exposed	1 / 20 (5.00%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Weight increased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Urine output increased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
White blood cells urine positive			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Cystogram			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Cardiac disorders			
Supraventricular extrasystoles			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Tachycardia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			

Thrombocytopenia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Cough			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Dyspnoea			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Epistaxis			
subjects affected / exposed	0 / 20 (0.00%)	1 / 28 (3.57%)	
occurrences (all)	0	1	
Nasal obstruction			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Oropharyngeal pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 20 (0.00%)	1 / 28 (3.57%)	
occurrences (all)	0	1	
Respiratory disorder			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Dry throat			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Rhinitis allergic			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Rhinorrhoea			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	

occurrences (all)	0	0	
Nasal congestion			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Headache			
subjects affected / exposed	0 / 20 (0.00%)	1 / 28 (3.57%)	
occurrences (all)	0	1	
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Cognitive disorder			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Syncope			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
Astigmatism			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Myopia			
subjects affected / exposed	0 / 20 (0.00%)	1 / 28 (3.57%)	
occurrences (all)	0	1	
Strabismus			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Vision blurred			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Accommodation disorder			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	

Eye pruritus			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Visual impairment			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Ear and labyrinth disorders			
Vertigo positional			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Ear pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Abdominal pain upper			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Constipation			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Diarrhoea			
subjects affected / exposed	1 / 20 (5.00%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Dry mouth			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Faeces soft			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Lip dry			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Nausea			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	

occurrences (all)	0	0	
Vomiting			
subjects affected / exposed	1 / 20 (5.00%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Toothache			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Abdominal discomfort			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Abdominal pain lower			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Dental caries			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Dysphagia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Enteritis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Flatulence			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Lip erythema			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Stomatitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Hypertonic bladder			

subjects affected / exposed	1 / 20 (5.00%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Incontinence			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Pollakiuria			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Renal failure			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Urinary incontinence			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Urine odour abnormal			
subjects affected / exposed	2 / 20 (10.00%)	0 / 28 (0.00%)	
occurrences (all)	2	0	
Urethral pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Urinary tract disorder			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Urine flow decreased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Decubitus ulcer			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Dermal cyst			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	

Dermatitis acneiform			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Dermatitis atopic			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Eczema			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Pruritus			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Seborrhoeic dermatitis			
subjects affected / exposed	1 / 20 (5.00%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Skin odour abnormal			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Urticaria			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Dermatitis allergic			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Rash macular			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Rash			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Pain in extremity			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	

occurrences (all)	0	0	
Spinal deformity			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Synovitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Arthritis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Joint contracture			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Muscular weakness			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Neck pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 20 (5.00%)	1 / 28 (3.57%)	
occurrences (all)	1	1	
Dehydration			
subjects affected / exposed	1 / 20 (5.00%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Polydipsia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
Asymptomatic bacteriuria			
subjects affected / exposed	3 / 20 (15.00%)	0 / 28 (0.00%)	
occurrences (all)	3	0	
Bacteriuria			
subjects affected / exposed	0 / 20 (0.00%)	1 / 28 (3.57%)	
occurrences (all)	0	1	

Conjunctivitis bacterial			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Escherichia urinary tract infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Gastroenteritis			
subjects affected / exposed	1 / 20 (5.00%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Gastroenteritis viral			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Hand-foot-and-mouth disease			
subjects affected / exposed	1 / 20 (5.00%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Impetigo			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Infection parasitic			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Influenza			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Mastitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Nasopharyngitis			
subjects affected / exposed	2 / 20 (10.00%)	1 / 28 (3.57%)	
occurrences (all)	3	1	
Oral herpes			
subjects affected / exposed	0 / 20 (0.00%)	1 / 28 (3.57%)	
occurrences (all)	0	1	
Pharyngitis			
subjects affected / exposed	1 / 20 (5.00%)	1 / 28 (3.57%)	
occurrences (all)	1	1	

Pyelonephritis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Rhinitis			
subjects affected / exposed	0 / 20 (0.00%)	1 / 28 (3.57%)	
occurrences (all)	0	1	
Sinusitis			
subjects affected / exposed	1 / 20 (5.00%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Tonsillitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Upper respiratory tract infection			
subjects affected / exposed	1 / 20 (5.00%)	2 / 28 (7.14%)	
occurrences (all)	1	2	
Urinary tract infection			
subjects affected / exposed	1 / 20 (5.00%)	4 / 28 (14.29%)	
occurrences (all)	1	4	
Varicella			
subjects affected / exposed	0 / 20 (0.00%)	1 / 28 (3.57%)	
occurrences (all)	0	1	
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Dermatitis infected			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Ear lobe infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Bronchitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Cellulitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	

Conjunctivitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Cystitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Cystitis bacterial			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Device related infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Ear infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Folliculitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Fungal skin infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Hordeolum			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Paronychia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Pharyngotonsillitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Scrotal infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	
Eye infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 28 (0.00%)	
occurrences (all)	0	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
03 March 2014	To enroll subjects <=25 kg as a separate cohort within the study who will be administered a beads-in capsule (BIC) formulation.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported