



Clinical trial results:

Summary

EudraCT number	0007-004076-38
Trial protocol	SE FR BE CZ ES FI GB NL AT HU IT DE
Global end of trial date	

Results information

Result version number	v1 (current)
This version publication date	
First version publication date	

Trial information

Trial identification

Sponsor protocol code	
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Additional study identifiers

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

Notes:

Sponsors

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	
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?	No

Notes:

Results analysis stage

Analysis stage	
Date of interim/final analysis	
Is this the analysis of the primary completion data?	
Global end of trial reached?	No

Notes:

General information about the trial

Main objective of the trial:

Protection of trial subjects:

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	
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Long term follow-up planned	No
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Independent data monitoring committee (IDMC) involvement?	
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Notes:

Population of trial subjects

Subjects enrolled per country

Notes:

Subjects enrolled per age group

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

Recruitment

Recruitment details: -

Pre-assignment

Screening details: -

Baseline characteristics

End points

End points reporting groups

Adverse events

Adverse events information

Timeframe for reporting adverse events:

EudraCT tool TEST upload

Adverse event reporting additional description:

EudraCT tool TEST upload

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	19.0
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Reporting groups

Reporting group title	Group A
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Reporting group description: -

Reporting group title	Group C
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Reporting group description: -

Reporting group title	Group B
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Reporting group description: -

Serious adverse events	Group A	Group C	Group B
Total subjects affected by serious adverse events			
subjects affected / exposed	10 / 20 (50.00%)	9 / 18 (50.00%)	13 / 22 (59.09%)
number of deaths (all causes)	3	2	6
number of deaths resulting from adverse events	3	2	6
Injury, poisoning and procedural complications			
Ankle fracture	Additional description: Ankle fracture		
subjects affected / exposed	5 / 20 (25.00%)	7 / 18 (38.89%)	6 / 22 (27.27%)
occurrences causally related to treatment / all	5 / 6	9 / 14	4 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Activated partial thromboplastin time prolonged	Additional description: Activated partial thromboplastin time prolonged		
subjects affected / exposed	4 / 20 (20.00%)	5 / 18 (27.78%)	6 / 22 (27.27%)
occurrences causally related to treatment / all	4 / 8	4 / 9	6 / 11
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Cardiac disorders			
Acute coronary syndrome	Additional description: Acute coronary syndrome		
subjects affected / exposed	3 / 20 (15.00%)	9 / 18 (50.00%)	4 / 22 (18.18%)
occurrences causally related to treatment / all	2 / 4	10 / 15	5 / 9

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Congenital, familial and genetic disorders - Other, specify	Additional description: Congenital, familial and genetic disorders - Other, specify		
subjects affected / exposed	5 / 20 (25.00%)	9 / 18 (50.00%)	4 / 22 (18.18%)
occurrences causally related to treatment / all	4 / 5	9 / 14	7 / 11
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Blood and lymphatic system disorders			
Anemia	Additional description: Anemia		
subjects affected / exposed	6 / 20 (30.00%)	3 / 18 (16.67%)	7 / 22 (31.82%)
occurrences causally related to treatment / all	2 / 6	1 / 13	7 / 16
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Abducens nerve disorder	Additional description: Abducens nerve disorder		
subjects affected / exposed	5 / 20 (25.00%)	3 / 18 (16.67%)	6 / 22 (27.27%)
occurrences causally related to treatment / all	5 / 8	4 / 7	4 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Blurred vision	Additional description: Blurred vision		
subjects affected / exposed	6 / 20 (30.00%)	4 / 18 (22.22%)	3 / 22 (13.64%)
occurrences causally related to treatment / all	4 / 16	1 / 7	2 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Ear pain	Additional description: Ear pain		
subjects affected / exposed	2 / 20 (10.00%)	4 / 18 (22.22%)	6 / 22 (27.27%)
occurrences causally related to treatment / all	4 / 9	6 / 10	4 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal distension	Additional description: Abdominal distension		
subjects affected / exposed	7 / 20 (35.00%)	2 / 18 (11.11%)	3 / 22 (13.64%)
occurrences causally related to treatment / all	2 / 8	3 / 8	4 / 4
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury	Additional description: Acute kidney injury		
subjects affected / exposed	4 / 20 (20.00%)	0 / 18 (0.00%)	5 / 22 (22.73%)
occurrences causally related to treatment / all	3 / 5	0 / 0	2 / 9

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Alopecia	Additional description: Alopecia		
subjects affected / exposed	3 / 20 (15.00%)	2 / 18 (11.11%)	8 / 22 (36.36%)
occurrences causally related to treatment / all	2 / 6	3 / 3	6 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Abdominal soft tissue necrosis	Additional description: Abdominal soft tissue necrosis		
subjects affected / exposed	5 / 20 (25.00%)	6 / 18 (33.33%)	4 / 22 (18.18%)
occurrences causally related to treatment / all	4 / 12	4 / 9	3 / 10
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency	Additional description: Adrenal insufficiency		
subjects affected / exposed	5 / 20 (25.00%)	3 / 18 (16.67%)	12 / 22 (54.55%)
occurrences causally related to treatment / all	4 / 12	2 / 8	10 / 17
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Metabolism and nutrition disorders			
Acidosis	Additional description: Acidosis		
subjects affected / exposed	8 / 20 (40.00%)	2 / 18 (11.11%)	5 / 22 (22.73%)
occurrences causally related to treatment / all	2 / 10	5 / 9	3 / 15
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Infections and infestations			
Abdominal infection	Additional description: Abdominal infection		
subjects affected / exposed	3 / 20 (15.00%)	4 / 18 (22.22%)	5 / 22 (22.73%)
occurrences causally related to treatment / all	3 / 7	4 / 10	1 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Capillary leak syndrome	Additional description: Capillary leak syndrome		
subjects affected / exposed	4 / 20 (20.00%)	9 / 18 (50.00%)	6 / 22 (27.27%)
occurrences causally related to treatment / all	8 / 12	10 / 16	1 / 11
deaths causally related to treatment / all	0 / 0	0 / 1	1 / 1
Surgical and medical procedures			
Surgical and medical procedures - Other, specify	Additional description: Surgical and medical procedures - Other, specify		
subjects affected / exposed	5 / 20 (25.00%)	3 / 18 (16.67%)	9 / 22 (40.91%)
occurrences causally related to treatment / all	3 / 5	4 / 7	9 / 16

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Leukemia secondary to oncology chemotherapy	Additional description: Leukemia secondary to oncology chemotherapy		
subjects affected / exposed	5 / 20 (25.00%)	8 / 18 (44.44%)	4 / 22 (18.18%)
occurrences causally related to treatment / all	5 / 8	8 / 12	6 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	2 / 2
Immune system disorders			
Allergic reaction	Additional description: Allergic reaction		
subjects affected / exposed	7 / 20 (35.00%)	7 / 18 (38.89%)	8 / 22 (36.36%)
occurrences causally related to treatment / all	3 / 10	5 / 11	4 / 13
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Social circumstances			
Menopause	Additional description: Menopause		
subjects affected / exposed	8 / 20 (40.00%)	6 / 18 (33.33%)	6 / 22 (27.27%)
occurrences causally related to treatment / all	5 / 12	5 / 6	5 / 12
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Fetal death	Additional description: Fetal death		
subjects affected / exposed	3 / 20 (15.00%)	4 / 18 (22.22%)	5 / 22 (22.73%)
occurrences causally related to treatment / all	4 / 7	2 / 8	11 / 14
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chills	Additional description: Chills		
subjects affected / exposed	10 / 20 (50.00%)	6 / 18 (33.33%)	7 / 22 (31.82%)
occurrences causally related to treatment / all	12 / 20	3 / 14	14 / 17
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Agitation	Additional description: Agitation		
subjects affected / exposed	6 / 20 (30.00%)	2 / 18 (11.11%)	10 / 22 (45.45%)
occurrences causally related to treatment / all	4 / 8	6 / 12	9 / 15
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Azoospermia	Additional description: Azoospermia		
subjects affected / exposed	5 / 20 (25.00%)	4 / 18 (22.22%)	3 / 22 (13.64%)

occurrences causally related to treatment / all	6 / 11	4 / 9	2 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Adult respiratory distress syndrome	Additional description: Adult respiratory distress syndrome		
subjects affected / exposed	7 / 20 (35.00%)	5 / 18 (27.78%)	12 / 22 (54.55%)
occurrences causally related to treatment / all	10 / 17	5 / 12	12 / 22
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile duct stenosis	Additional description: Bile duct stenosis		
subjects affected / exposed	5 / 20 (25.00%)	1 / 18 (5.56%)	9 / 22 (40.91%)
occurrences causally related to treatment / all	1 / 5	0 / 6	8 / 16
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Group A	Group C	Group B
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 20 (50.00%)	11 / 18 (61.11%)	14 / 22 (63.64%)
Injury, poisoning and procedural complications			
Ankle fracture	Additional description: Ankle fracture		
subjects affected / exposed	5 / 20 (25.00%)	8 / 18 (44.44%)	4 / 22 (18.18%)
occurrences (all)	9	17	14
Investigations			
Activated partial thromboplastin time prolonged	Additional description: Activated partial thromboplastin time prolonged		
subjects affected / exposed	6 / 20 (30.00%)	2 / 18 (11.11%)	6 / 22 (27.27%)
occurrences (all)	8	7	14
Cardiac disorders			
Acute coronary syndrome	Additional description: Acute coronary syndrome		
subjects affected / exposed	4 / 20 (20.00%)	3 / 18 (16.67%)	11 / 22 (50.00%)
occurrences (all)	12	6	15
Congenital, familial and genetic disorders			
Congenital, familial and genetic disorders - Other, specify	Additional description: Congenital, familial and genetic disorders - Other, specify		
subjects affected / exposed	2 / 20 (10.00%)	7 / 18 (38.89%)	6 / 22 (27.27%)
occurrences (all)	4	7	11

Blood and lymphatic system disorders			
Anemia	Additional description: Anemia		
subjects affected / exposed	3 / 20 (15.00%)	5 / 18 (27.78%)	6 / 22 (27.27%)
occurrences (all)	10	11	14
Nervous system disorders			
Abducens nerve disorder	Additional description: Abducens nerve disorder		
subjects affected / exposed	7 / 20 (35.00%)	8 / 18 (44.44%)	8 / 22 (36.36%)
occurrences (all)	17	18	11
Eye disorders			
Blurred vision	Additional description: Blurred vision		
subjects affected / exposed	2 / 20 (10.00%)	8 / 18 (44.44%)	6 / 22 (27.27%)
occurrences (all)	7	16	9
Ear and labyrinth disorders			
Ear pain	Additional description: Ear pain		
subjects affected / exposed	8 / 20 (40.00%)	5 / 18 (27.78%)	7 / 22 (31.82%)
occurrences (all)	18	8	16
Gastrointestinal disorders			
Abdominal distension	Additional description: Abdominal distension		
subjects affected / exposed	7 / 20 (35.00%)	7 / 18 (38.89%)	8 / 22 (36.36%)
occurrences (all)	11	13	16
Renal and urinary disorders			
Acute kidney injury	Additional description: Acute kidney injury		
subjects affected / exposed	2 / 20 (10.00%)	5 / 18 (27.78%)	11 / 22 (50.00%)
occurrences (all)	7	11	21
Skin and subcutaneous tissue disorders			
Alopecia	Additional description: Alopecia		
subjects affected / exposed	4 / 20 (20.00%)	5 / 18 (27.78%)	5 / 22 (22.73%)
occurrences (all)	5	15	11
Musculoskeletal and connective tissue disorders			
Abdominal soft tissue necrosis	Additional description: Abdominal soft tissue necrosis		
subjects affected / exposed	4 / 20 (20.00%)	9 / 18 (50.00%)	3 / 22 (13.64%)
occurrences (all)	10	11	11
Endocrine disorders			
Adrenal insufficiency	Additional description: Adrenal insufficiency		
subjects affected / exposed	10 / 20 (50.00%)	4 / 18 (22.22%)	5 / 22 (22.73%)
occurrences (all)	18	4	11
Metabolism and nutrition disorders			

Acidosis subjects affected / exposed occurrences (all)	Additional description: Acidosis		
	6 / 20 (30.00%) 14	11 / 18 (61.11%) 18	5 / 22 (22.73%) 8
Infections and infestations Abdominal infection subjects affected / exposed occurrences (all)	Additional description: Abdominal infection		
	4 / 20 (20.00%) 9	3 / 18 (16.67%) 4	4 / 22 (18.18%) 14
Vascular disorders Capillary leak syndrome subjects affected / exposed occurrences (all)	Additional description: Capillary leak syndrome		
	2 / 20 (10.00%) 8	7 / 18 (38.89%) 8	5 / 22 (22.73%) 5
Surgical and medical procedures Surgical and medical procedures - Other, specify subjects affected / exposed occurrences (all)	Additional description: Surgical and medical procedures - Other, specify		
	6 / 20 (30.00%) 15	4 / 18 (22.22%) 14	4 / 22 (18.18%) 10
Neoplasms benign, malignant and unspecified (incl cysts and polyps) Leukemia secondary to oncology chemotherapy subjects affected / exposed occurrences (all)	Additional description: Leukemia secondary to oncology chemotherapy		
	4 / 20 (20.00%) 5	5 / 18 (27.78%) 14	4 / 22 (18.18%) 13
Immune system disorders Allergic reaction subjects affected / exposed occurrences (all)	Additional description: Allergic reaction		
	4 / 20 (20.00%) 5	3 / 18 (16.67%) 8	9 / 22 (40.91%) 17
Social circumstances Menopause subjects affected / exposed occurrences (all)	Additional description: Menopause		
	8 / 20 (40.00%) 14	1 / 18 (5.56%) 3	7 / 22 (31.82%) 7
Pregnancy, puerperium and perinatal conditions Fetal death subjects affected / exposed occurrences (all)	Additional description: Fetal death		
	4 / 20 (20.00%) 7	6 / 18 (33.33%) 7	14 / 22 (63.64%) 22
General disorders and administration site conditions Chills subjects affected / exposed occurrences (all)	Additional description: Chills		
	3 / 20 (15.00%) 6	10 / 18 (55.56%) 15	5 / 22 (22.73%) 8
Psychiatric disorders			

Agitation subjects affected / exposed occurrences (all)	Additional description: Agitation		
	5 / 20 (25.00%) 5	7 / 18 (38.89%) 8	4 / 22 (18.18%) 7
Reproductive system and breast disorders Azoospermia subjects affected / exposed occurrences (all)	Additional description: Azoospermia		
	8 / 20 (40.00%) 16	6 / 18 (33.33%) 11	6 / 22 (27.27%) 15
Respiratory, thoracic and mediastinal disorders Adult respiratory distress syndrome subjects affected / exposed occurrences (all)	Additional description: Adult respiratory distress syndrome		
	4 / 20 (20.00%) 7	8 / 18 (44.44%) 14	3 / 22 (13.64%) 6
Hepatobiliary disorders Bile duct stenosis subjects affected / exposed occurrences (all)	Additional description: Bile duct stenosis		
	4 / 20 (20.00%) 7	3 / 18 (16.67%) 9	8 / 22 (36.36%) 16

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol?

Interruptions (globally)

Were there any global interruptions to the trial?

Limitations and caveats

None reported