Summary of Results for Laypersons

What was the Study Called?

A Multicenter, Open-label, Single Ascending Dose Study to Evaluate Pharmacokinetics, Safety and Tolerability of Solifenacin Succinate Suspension in Pediatric Patients Aged 5 to 17 Years (Inclusive) with Overactive Bladder

Why was this Study Needed?

People with overactive bladder have symptoms such as:

- Sudden need to urinate which is difficult to delay (called urinary urgency).
- Having to empty the bladder more often than usual (called increased urinary frequency).
- Any loss of urine due to not being able to control when to empty the bladder (called urinary incontinence).

There are medicines for adults with overactive bladder. These include solifenacin succinate (also known as YM905 and VESIcare®). It comes in tablets. Tablets can be difficult to swallow for children. A liquid form of solifenacin succinate was made for children to take by mouth.

This study tested the liquid form (called solifenacin succinate suspension) in children and teenagers with overactive bladder. This study helped answer how well the liquid form is absorbed into the body and how long it stays in the body. It was also important to find out what unwanted effects these patients had from the study medicine. This study was not designed to test whether the study medicine was useful or effective.

This study took place at 12 clinics in Belgium, Denmark, Norway, Poland, Sweden and the UK. The study took place from October 2010 to August 2011. When the study ended, the sponsor (Astellas) reviewed all the study information and created a report of the results. This is a summary of that report.

What Kind of Study was This and Who Took Part in it?

This was an "open-label" study. All patients knew that they took solifenacin succinate suspension.

This was also a "dose escalation" study. The first patients who were treated took a single low dose of study medicine. The study doctor checked these patients. If no safety issues were seen, then the next patients took a single intermediate dose of study medicine. The study doctor checked these patients. If no safety issues were seen, then the next patients took a single high dose of study medicine. The doses of solifenacin succinate suspension were based on body weight.

- The low dose was comparable to 2.5 mg of solifenacin succinate tablets taken once daily in adults.
- The intermediate dose was comparable to 5 mg of solifenacin succinate tablets taken once daily in adults.

- The high dose was comparable to 10 mg of solifenacin succinate tablets taken once daily in adults.

Children and teenagers with overactive bladder could take part in the study if:

- The children were 5 to 11 years old and the teenagers were 12 to 17 years old.
- They were not able to control when to empty their bladder at least once during the day.
- They had a normal weight and height for their age.

Patients could not take part in this study if:

- They had to urinate less than 5 times during the day.
- They had to urinate at least once every hour during the day. The amount of urine was less than 50% of what their bladder could hold.
- The cause of their bladder problems was not overactive bladder.
- The maximum amount of their urine was greater than a protocol specified number.
- The amount of urine left in their bladder after urination was more than 10% of what their bladder could hold.

Patients who were taking medicine for their bladder problems went off their medicine for at least 2 weeks before the treatment day. On the morning of the treatment day (day 1), the patients arrived at the clinic. Patients were checked to see if they could be in the study. Patients who could be in the study took a single dose of solifenacin succinate suspension. All patients gave blood samples after they took study medicine. Patients returned to the clinic for blood samples on days 3, 5 and 7.

A total of 42 patients were in this study. All patients took study medicine.

	Number of Patients (out of 42 patients)
Age Group	
Aged 5 to 11 years	22
Aged 12 to 17 years	20
Gender	
Girls	23
Boys	19
Clinic Location	
EU Countries	
Belgium	19
Denmark	10
Poland	3
Sweden	3
The UK	6
Outside EU	
Norway	1

What Were the Study Results?

The study showed that levels of solifenacin succinate in blood increased with dose. There was no clear difference in those blood levels between children and teenagers.

The study showed that children and teenagers with overactive bladder who took solifenacin succinate suspension did not have a lot of unwanted effects. This was the case for all doses of study medicine that were tested.

What Adverse Reactions did Patients Have?

A lot of research is needed to know whether a medicine causes a medical problem. So when new medicines are being studied researchers keep track of all medical problems that patients have while they are in the study. These medical problems are called "adverse events" and are recorded whether or not they might be caused by the treatment taken. An "adverse reaction" is any medical problem or "adverse event" that is judged by the study doctor to be possibly caused by a medicine or treatment used in the study.

Specific adverse reactions (belly pain above the belly button, dry mouth, fatigue or tiredness, back pain and rash) occurred in 1 patient each.

An adverse reaction is considered "serious" when it is life-threatening, causes lasting problems, or needs hospital care. None of the patients had a serious adverse reaction.

None of the patients died during the study.

Where Can I Learn More About This Study?

Astellas might perform additional trials to better understand solifenacin succinate.

This summary of the clinical study results is available online at http://www.astellasclinicalstudyresults.com. Please remember that researchers look at the results of many studies to find out how well medicines work and which adverse reactions they might cause. If you have questions about solifenacin succinate, please discuss these with your doctor.

Sponsor contact details:

Astellas Pharma Europe B.V.
Sylviusweg 62
2333 BE Leiden
The Netherlands