



Clinical trial results:

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

Summary

EudraCT number	2009-017197-21
Trial protocol	BE GB DK SE NO PL
Global end of trial date	14 August 2011

Results information

Result version number	v1 (current)
This version publication date	01 April 2016
First version publication date	11 July 2015

Trial information

Trial identification

Sponsor protocol code	905-CL-075
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01262391
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Astellas Pharma Europe B.V.
Sponsor organisation address	Sylviusweg 62, Leiden, Netherlands, 2333 BE
Public contact	Clinical Trial Disclosure, Astellas Pharma Global Development, Inc., Astellas.resultsdisclosure@astellas.com
Scientific contact	Clinical Trial Disclosure, Astellas Pharma Global Development, Inc., Astellas.resultsdisclosure@astellas.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMA-000573-PIP01-09
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	14 August 2011
Is this the analysis of the primary completion data?	Yes
Primary completion date	14 August 2011
Global end of trial reached?	Yes
Global end of trial date	14 August 2011
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the pharmacokinetics (PK) of solifenacin succinate suspension after single-dose administration at different dose levels in children and adolescents with overactive bladder (OAB).

Protection of trial subjects:

This clinical study was written, conducted and reported in accordance with the protocol, ICH GCP Guidelines, and applicable local regulations, including the European Directive 2001/20/EC, on the protection of human rights, and with the ethical principles that have their origin in the Declaration of Helsinki.

Astellas ensures that the use and disclosure of protected health information (PHI) obtained during a research study complies with the federal, national and/or regional legislation related to the privacy and protection of personal information.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	20 October 2010
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Norway: 1
Country: Number of subjects enrolled	Poland: 3
Country: Number of subjects enrolled	Sweden: 3
Country: Number of subjects enrolled	United Kingdom: 6
Country: Number of subjects enrolled	Belgium: 19
Country: Number of subjects enrolled	Denmark: 10
Worldwide total number of subjects	42
EEA total number of subjects	42

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)	22
Adolescents (12-17 years)	20
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:

Children and adolescents with OAB, who consented to enter this study and fulfilled all the eligibility criteria, were enrolled in the study. A wash out period of 14 days was performed prior to study drug treatment.

Period 1

Period 1 title	Overall study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	AD-PED 2.5 mg

Arm description:

Male and female adolescents aged 12 to less than 18 years old who received pediatric equivalent dose (PED) of 2.5 mg of solifenacin succinate.

Arm type	Experimental
Investigational medicinal product name	Solifenacin succinate suspension
Investigational medicinal product code	YM905
Other name	
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

Adolescents were given a single dose of solifenacin succinate liquid suspension orally via syringe in the morning of day 1 followed by a glass of water. Doses were calculated per weight of the participant, targeting to have equivalent dose of 2.5 mg dose of solifenacin once daily in adults (referred to as PED of 2.5 mg).

Arm title	AD-PED 5 mg
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Arm description:

Male and female adolescents aged 12 to less than 18 years old who received PED of 5 mg of solifenacin succinate.

Arm type	Experimental
Investigational medicinal product name	Solifenacin succinate suspension
Investigational medicinal product code	YM905
Other name	
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

Adolescents were given a single dose of solifenacin liquid suspension succinate orally via syringe in the morning of day 1 followed by a glass of water. Doses were calculated per weight of the participant, targeting to have equivalent dose of 5 mg dose of solifenacin once daily in adults (referred to as PED of 5 mg).

Arm title	AD-PED 10 mg
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Arm description:

Male and female adolescents aged 12 to less than 18 years old who received PED of 10 mg of solifenacin succinate.

Arm type	Experimental
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Investigational medicinal product name	Solifenacin succinate suspension
Investigational medicinal product code	YM905
Other name	
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

Adolescents were given a single dose of solifenacin succinate liquid suspension orally via syringe in the morning of day 1 followed by a glass of water. Doses were calculated per weight of the participant, targeting to have equivalent dose of 10 mg dose of solifenacin once daily in adults (referred to as PED of 10 mg).

Arm title	CH-PED 2.5 mg
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Arm description:

Male and female children aged 5 to less than 12 years old who received PED of 2.5 mg of solifenacin succinate.

Arm type	Experimental
Investigational medicinal product name	Solifenacin succinate suspension
Investigational medicinal product code	YM905
Other name	
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

Children were given a single dose of solifenacin succinate liquid suspension orally via syringe in the morning of day 1 followed by a glass of water. Doses were calculated per weight of the participant, targeting to have equivalent dose of 2.5 mg dose of solifenacin once daily in adults (referred to as PED of 2.5 mg).

Arm title	CH-PED 5 mg
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Arm description:

Male and female children aged 5 to less than 12 years old who received PED of 5 mg of solifenacin succinate.

Arm type	Experimental
Investigational medicinal product name	Solifenacin succinate suspension
Investigational medicinal product code	YM905
Other name	
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

Children were given a single dose of solifenacin liquid suspension orally via syringe in the morning of day 1 followed by a glass of water. Doses were calculated per weight of the participant, targeting to have equivalent dose of 5 mg dose of solifenacin once daily in adults (referred to as PED of 5 mg).

Arm title	CH-PED 10 mg
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Arm description:

Male and female children aged 5 to less than 12 years old who received PED of 10 mg of solifenacin succinate.

Arm type	Experimental
Investigational medicinal product name	Solifenacin succinate suspension
Investigational medicinal product code	YM905
Other name	
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

Children were given a single dose of solifenacin succinate liquid suspension orally via syringe in the morning of day 1 followed by a glass of water. Doses were calculated per weight of the participant, targeting to have equivalent dose of 10 mg dose of solifenacin once daily in adults (referred to as PED of 10 mg).

Number of subjects in period 1	AD-PED 2.5 mg	AD-PED 5 mg	AD-PED 10 mg
Started	6	6	8
Treated	6	6	8
Completed	6	6	8

Number of subjects in period 1	CH-PED 2.5 mg	CH-PED 5 mg	CH-PED 10 mg
Started	8	8	6
Treated	8	8	6
Completed	8	8	6

Baseline characteristics

Reporting groups

Reporting group title	AD-PED 2.5 mg
Reporting group description: Male and female adolescents aged 12 to less than 18 years old who received pediatric equivalent dose (PED) of 2.5 mg of solifenacin succinate.	
Reporting group title	AD-PED 5 mg
Reporting group description: Male and female adolescents aged 12 to less than 18 years old who received PED of 5 mg of solifenacin succinate.	
Reporting group title	AD-PED 10 mg
Reporting group description: Male and female adolescents aged 12 to less than 18 years old who received PED of 10 mg of solifenacin succinate.	
Reporting group title	CH-PED 2.5 mg
Reporting group description: Male and female children aged 5 to less than 12 years old who received PED of 2.5 mg of solifenacin succinate.	
Reporting group title	CH-PED 5 mg
Reporting group description: Male and female children aged 5 to less than 12 years old who received PED of 5 mg of solifenacin succinate.	
Reporting group title	CH-PED 10 mg
Reporting group description: Male and female children aged 5 to less than 12 years old who received PED of 10 mg of solifenacin succinate.	

Reporting group values	AD-PED 2.5 mg	AD-PED 5 mg	AD-PED 10 mg
Number of subjects	6	6	8
Age categorical Units: Subjects			

Age continuous Units: years arithmetic mean standard deviation	13.2 ± 1.17	14.2 ± 1.47	13.3 ± 1.91
Gender categorical Units: Subjects			
Female	6	4	5
Male	0	2	3

Reporting group values	CH-PED 2.5 mg	CH-PED 5 mg	CH-PED 10 mg
Number of subjects	8	8	6
Age categorical Units: Subjects			

Age continuous Units: years arithmetic mean	8.4	7.4	7.3
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standard deviation	± 1.77	± 2	± 0.82
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Gender categorical Units: Subjects			
Female	4	2	2
Male	4	6	4

Reporting group values	Total		
Number of subjects	42		
Age categorical Units: Subjects			

Age continuous Units: years arithmetic mean standard deviation	-		
Gender categorical Units: Subjects			
Female	23		
Male	19		

End points

End points reporting groups

Reporting group title	AD-PED 2.5 mg
Reporting group description: Male and female adolescents aged 12 to less than 18 years old who received pediatric equivalent dose (PED) of 2.5 mg of solifenacin succinate.	
Reporting group title	AD-PED 5 mg
Reporting group description: Male and female adolescents aged 12 to less than 18 years old who received PED of 5 mg of solifenacin succinate.	
Reporting group title	AD-PED 10 mg
Reporting group description: Male and female adolescents aged 12 to less than 18 years old who received PED of 10 mg of solifenacin succinate.	
Reporting group title	CH-PED 2.5 mg
Reporting group description: Male and female children aged 5 to less than 12 years old who received PED of 2.5 mg of solifenacin succinate.	
Reporting group title	CH-PED 5 mg
Reporting group description: Male and female children aged 5 to less than 12 years old who received PED of 5 mg of solifenacin succinate.	
Reporting group title	CH-PED 10 mg
Reporting group description: Male and female children aged 5 to less than 12 years old who received PED of 10 mg of solifenacin succinate.	

Primary: Maximum concentration (C_{max})

End point title	Maximum concentration (C _{max}) ^[1]
End point description: The analysis population was the pharmacokinetic analysis set (PKAS), defined as all participants who received the dose of study drug and who had values of concentration for a sufficient number of time points to calculate reliably at least 1 pharmacokinetic parameter. The number of samples as well sampling times depended on the age of the participant (aged 5-8 years old: 4 samples; aged 9-11 years old: 6 samples; aged 12-17 years old: 7 samples).	
End point type	Primary
End point timeframe: Day 1 predose up to Day 7 postdose	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This study was written with no planned statistical analyses (statistical hypothesis testing) to be performed for any end points due to the simple design and purpose of the study.

End point values	AD-PED 2.5 mg	AD-PED 5 mg	AD-PED 10 mg	CH-PED 2.5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	6	8	5
Units: ng/mL				
arithmetic mean (standard deviation)	7.97 (± 4.23)	17.1 (± 3.9)	29.7 (± 8.7)	8.34 (± 2.11)

End point values	CH-PED 5 mg	CH-PED 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	5		
Units: ng/mL				
arithmetic mean (standard deviation)	18.5 (± 6.4)	42.3 (± 29.8)		

Statistical analyses

No statistical analyses for this end point

Primary: Area under the curve extrapolated to infinity (AUCinf)

End point title	Area under the curve extrapolated to infinity (AUCinf) ^[2]
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End point description:

The analysis population was the PKAS. The number of samples as well sampling times depended on the age of the participant (aged 5-8 years old: 4 samples; aged 9-11 years old: 6 samples; aged 12-17 years old: 7 samples).

End point type	Primary
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End point timeframe:

Day 1 predose up to Day 7 postdose

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This study was written with no planned statistical analyses (statistical hypothesis testing) to be performed for any end points due to the simple design and purpose of the study.

End point values	AD-PED 2.5 mg	AD-PED 5 mg	AD-PED 10 mg	CH-PED 2.5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	6	8	5
Units: ng*h/mL				
arithmetic mean (standard deviation)	446 (± 296)	752 (± 228)	1458 (± 969)	365 (± 146)

End point values	CH-PED 5 mg	CH-PED 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	5		
Units: ng*h/mL				
arithmetic mean (standard deviation)	657 (± 236)	2331 (± 2882)		

Statistical analyses

No statistical analyses for this end point

Primary: Apparent terminal elimination half-life (t_{1/2})

End point title	Apparent terminal elimination half-life (t _{1/2}) ^[3]
End point description: The analysis population was the PKAS. The number of samples as well sampling times depended on the age of the participant (aged 5-8 years old: 4 samples; aged 9-11 years old: 6 samples; aged 12-17 years old: 7 samples).	
End point type	Primary
End point timeframe: Day 1 predose up to Day 7 postdose	

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This study was written with no planned statistical analyses (statistical hypothesis testing) to be performed for any end points due to the simple design and purpose of the study.

End point values	AD-PED 2.5 mg	AD-PED 5 mg	AD-PED 10 mg	CH-PED 2.5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	6	8	5
Units: hours				
arithmetic mean (standard deviation)	37.1 (± 5.4)	32.2 (± 4.8)	33.3 (± 11.4)	27.5 (± 7.5)

End point values	CH-PED 5 mg	CH-PED 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	5		
Units: hours				
arithmetic mean (standard deviation)	23.4 (± 2.6)	39.2 (± 35)		

Statistical analyses

No statistical analyses for this end point

Primary: Time to attain C_{max} (t_{max})

End point title	Time to attain C _{max} (t _{max}) ^[4]
End point description: The analysis population was the PKAS. The number of samples as well sampling times depended on the age of the participant (aged 5-8 years old: 4 samples; aged 9-11 years old: 6 samples; aged 12-17 years old: 7 samples).	
End point type	Primary
End point timeframe: Day 1 predose up to Day 7 postdose	

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This study was written with no planned statistical analyses (statistical hypothesis testing) to be performed for any end points due to the simple design and purpose of the study.

End point values	AD-PED 2.5 mg	AD-PED 5 mg	AD-PED 10 mg	CH-PED 2.5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	6	8	5
Units: hours				
arithmetic mean (standard deviation)	4.31 (± 0.93)	3.51 (± 0.33)	3.77 (± 0.58)	4.08 (± 0.38)

End point values	CH-PED 5 mg	CH-PED 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	5		
Units: hours				
arithmetic mean (standard deviation)	3.37 (± 1.17)	3.56 (± 1.8)		

Statistical analyses

No statistical analyses for this end point

Primary: Apparent total body clearance (CL/F)

End point title	Apparent total body clearance (CL/F) ^[5]
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End point description:

The analysis population was the PKAS. The number of samples as well sampling times depended on the age of the participant (aged 5-8 years old: 4 samples; aged 9-11 years old: 6 samples; aged 12-17 years old: 7 samples).

End point type	Primary
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End point timeframe:

Day 1 predose up to Day 7 postdose

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This study was written with no planned statistical analyses (statistical hypothesis testing) to be performed for any end points due to the simple design and purpose of the study.

End point values	AD-PED 2.5 mg	AD-PED 5 mg	AD-PED 10 mg	CH-PED 2.5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	6	8	5
Units: L/h				
arithmetic mean (standard deviation)	15.9 (± 11.8)	13.1 (± 4.1)	15.2 (± 6.3)	9.95 (± 7.68)

End point values	CH-PED 5 mg	CH-PED 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	5		
Units: L/h				
arithmetic mean (standard deviation)	8.62 (± 5.33)	7.56 (± 3.66)		

Statistical analyses

No statistical analyses for this end point

Primary: Apparent volume of distribution during the terminal phase (V_z/F)

End point title	Apparent volume of distribution during the terminal phase (V_z/F) ^[6]
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End point description:

The analysis population was the PKAS. The number of samples as well sampling times depended on the age of the participant (aged 5-8 years old: 4 samples; aged 9-11 years old: 6 samples; aged 12-17 years old: 7 samples).

End point type	Primary
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End point timeframe:

Day 1 predose up to Day 7 postdose

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This study was written with no planned statistical analyses (statistical hypothesis testing) to be performed for any end points due to the simple design and purpose of the study.

End point values	AD-PED 2.5 mg	AD-PED 5 mg	AD-PED 10 mg	CH-PED 2.5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	6	8	5
Units: liters				
arithmetic mean (standard deviation)	804 (± 572)	609 (± 201)	652 (± 151)	381 (± 277)

End point values	CH-PED 5 mg	CH-PED 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	5		
Units: liters				
arithmetic mean (standard deviation)	288 (± 177)	311 (± 155)		

Statistical analyses

No statistical analyses for this end point

Primary: Area under the concentration-time curve from the time of dosing until the last measurable concentration (AUClast)

End point title	Area under the concentration-time curve from the time of dosing until the last measurable concentration (AUClast) ^[7]
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End point description:

The analysis population was the PKAS. The number of samples as well sampling times depended on the age of the participant (aged 5-8 years old: 4 samples; aged 9-11 years old: 6 samples; aged 12-17 years old: 7 samples).

End point type	Primary
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End point timeframe:

Day 1 predose up to Day 7 postdose

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This study was written with no planned statistical analyses (statistical hypothesis testing) to be performed for any end points due to the simple design and purpose of the study.

End point values	AD-PED 2.5 mg	AD-PED 5 mg	AD-PED 10 mg	CH-PED 2.5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[8]	0 ^[9]	0 ^[10]	0 ^[11]
Units: ng*h/mL				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[8] - AUClast was not calculated since non-compartmental modeling was not used for PK analysis.

[9] - AUClast was not calculated since non-compartmental modeling was not used for PK analysis.

[10] - AUClast was not calculated since non-compartmental modeling was not used for PK analysis.

[11] - AUClast was not calculated since non-compartmental modeling was not used for PK analysis.

End point values	CH-PED 5 mg	CH-PED 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[12]	0 ^[13]		
Units: ng*h/mL				
arithmetic mean (standard deviation)	()	()		

Notes:

[12] - AUClast was not calculated since non-compartmental modeling was not used for PK analysis.

[13] - AUClast was not calculated since non-compartmental modeling was not used for PK analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: Safety as assessed by adverse events (AEs), vital signs, clinical laboratory tests, physical examination and electrocardiograms (ECGs)

End point title	Safety as assessed by adverse events (AEs), vital signs, clinical laboratory tests, physical examination and electrocardiograms (ECGs)
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End point description:

Safety was monitored by collecting AEs, which included abnormal laboratory tests, vital signs or ECG data that were defined as an AE if the abnormality induced clinical signs or symptoms, required active intervention, interruption or discontinuation of study medication or was clinically significant in the investigator's opinion. A treatment-emergent adverse event (TEAE) was defined as an AE that occurred or worsened after study drug administration. A serious AE (SAE) was any untoward medical occurrence that, at any dose: Resulted in death, was life-threatening, resulted in persistent or significant disability/incapacity, resulted in congenital anomaly, or birth defect, required inpatient hospitalization or led to prolongation of hospitalization or other medically important events. The analysis population was the safety analysis set (SAF), which consisted of all enrolled participants who received the dose of study drug.

End point type	Secondary
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End point timeframe:

From the first dose of study drug up to 7 days postdose

End point values	AD-PED 2.5 mg	AD-PED 5 mg	AD-PED 10 mg	CH-PED 2.5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	6	8	8
Units: participants				
Incidence of AEs	0	2	2	3
Number of AEs	0	2	2	3
Incidence of drug-related AEs	0	1	2	0
Number of drug-related AEs	0	1	2	0
Incidence of deaths	0	0	0	0
Incidence of SAEs	0	0	0	0
Number of SAEs	0	0	0	0
Incidence of drug-related SAEs	0	0	0	0
Number of drug-related SAEs	0	0	0	0
Incidence of AEs leading to discontinuation	0	0	0	0
Incidence of drug-related AEs leading to discount.	0	0	0	0

End point values	CH-PED 5 mg	CH-PED 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	6		
Units: participants				
Incidence of AEs	1	1		
Number of AEs	2	1		
Incidence of drug-related AEs	1	1		
Number of drug-related AEs	1	1		
Incidence of deaths	0	0		
Incidence of SAEs	0	0		
Number of SAEs	0	0		
Incidence of drug-related SAEs	0	0		
Number of drug-related SAEs	0	0		
Incidence of AEs leading to discontinuation	0	0		
Incidence of drug-related AEs leading to discount.	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in postvoid residual (PVR) volume

End point title	Change from baseline in postvoid residual (PVR) volume
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End point description:

PVR volume was assessed by ultrasonography or bladder scan. The analysis population was the SAF.

End point type	Secondary
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End point timeframe:

Baseline (screening) and 4 hours postdose

End point values	AD-PED 2.5 mg	AD-PED 5 mg	AD-PED 10 mg	CH-PED 2.5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	6	8	8
Units: mL				
arithmetic mean (standard deviation)	-4.5 (\pm 8.09)	3 (\pm 6.96)	-2.9 (\pm 8.13)	5.1 (\pm 14.99)

End point values	CH-PED 5 mg	CH-PED 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	6		
Units: mL				
arithmetic mean (standard deviation)	-0.1 (\pm 7.38)	2 (\pm 6.93)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From the first dose of study drug up to 7 days postdose

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	13.0
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Reporting groups

Reporting group title	AD-PED 2.5 mg
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Reporting group description:

Male and female adolescents aged 12 to less than 18 years old who received PED of 2.5 mg of solifenacin.

Reporting group title	AD-PED 5 mg
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Reporting group description:

Male and female adolescents aged 12 to less than 18 years old who received PED of 5 mg of solifenacin.

Reporting group title	AD-PED 10 mg
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Reporting group description:

Male and female adolescents aged 12 to less than 18 years old who received PED of 10 mg of solifenacin.

Reporting group title	CH-PED 2.5 mg
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Reporting group description:

Male and female children aged 5 to less than 12 years old who received PED of 2.5 mg of solifenacin.

Reporting group title	CH-PED 5 mg
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Reporting group description:

Male and female children aged 5 to less than 12 years old who received PED of 5 mg of solifenacin.

Reporting group title	CH-PED 10 mg
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Reporting group description:

Male and female children aged 5 to less than 12 years old who received PED of 10 mg of solifenacin.

Serious adverse events	AD-PED 2.5 mg	AD-PED 5 mg	AD-PED 10 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			

Serious adverse events	CH-PED 2.5 mg	CH-PED 5 mg	CH-PED 10 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 6 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			

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

Non-serious adverse events	AD-PED 2.5 mg	AD-PED 5 mg	AD-PED 10 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 6 (0.00%)	2 / 6 (33.33%)	2 / 8 (25.00%)
Investigations			
Eosinophil count increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			

Residual urine subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Musculoskeletal and connective tissue disorders			
Back pain subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0	1 / 8 (12.50%) 1
Groin pain subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0

Non-serious adverse events	CH-PED 2.5 mg	CH-PED 5 mg	CH-PED 10 mg
Total subjects affected by non-serious adverse events subjects affected / exposed	3 / 8 (37.50%)	1 / 8 (12.50%)	1 / 6 (16.67%)
Investigations Eosinophil count increased subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	1 / 8 (12.50%) 1	0 / 6 (0.00%) 0
Nervous system disorders Headache subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0	0 / 6 (0.00%) 0
General disorders and administration site conditions Fatigue subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0	0 / 6 (0.00%) 0
Gastrointestinal disorders Abdominal pain upper subjects affected / exposed occurrences (all) Dry mouth subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0 0 / 8 (0.00%) 0	0 / 8 (0.00%) 0 0 / 8 (0.00%) 0	1 / 6 (16.67%) 1 0 / 6 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Oropharyngeal pain subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1	0 / 8 (0.00%) 0	0 / 6 (0.00%) 0

Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 8 (0.00%)	1 / 8 (12.50%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
Residual urine			
subjects affected / exposed	1 / 8 (12.50%)	0 / 8 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 8 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported