Clinical trial results:
Long-term Extension Study to Evaluate the Safety of Fesoterodine in Japanese Pediatric Subjects With Symptoms of Detrusor Overactivity Associated With a Neurological Condition (Neurogenic Detrusor Overactivity) who Have Completed 24 Weeks Treatment in Study A0221047

Summary

EudraCT number	2020-004192-41
Trial protocol	Outside EU/EEA
Global end of trial date	01 April 2020

Results information

Result version number	v1 (current)
This version publication date	11 October 2020
First version publication date	11 October 2020

Trial information

Trial identification

Sponsor protocol code	A0221109

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, 10017
Public contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., +1 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., +1 8007181021, 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	13 August 2020
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	01 April 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To investigate the safety and tolerability of fesoterodine following once daily longterm treatment in Japanese pediatric subjects.

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 Harmonisation (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	05 June 2015
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	Japan: 12
Worldwide total number of subjects	12
EEA total number of subjects	0

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)	10
Adolescents (12-17 years)	2
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This (A0221109) was a long term extension (LTE) study only among Japanese subjects who participated and completed the precedent study A0221047 (NCT01557244). Per plan, efficacy outcome measures and treatment-emergent adverse events were reported using merged data of studies A0221047 and A0221109.

Pre-assignment

Screening details:

A0221047 had 2 cohorts. Cohort 1 had an active comparator phase and Cohort 2 had an efficacy phase followed by a safety extension phase for each cohort. Japanese subjects from both cohorts, if consented continued in this LTE study and received the same treatment as in A0221047, per investigator judgment on safety and tolerance of subjects.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Fesoterodine 8 mg Tablet

Arm description:

In precedent study A0221047, subject of cohort 1, with body weight greater than (>) 25 kilogram (kg), received fesoterodine 4 milligram (mg) prolonged release (PR) tablet once daily for 1 week and if well tolerated then fesoterodine 8 mg PR tablet once daily for 11 weeks in active comparator phase and 12 weeks in safety extension phase. Only Japanese subject who consented to continue in this LTE study, were to receive fesoterodine 8 mg PR tablet orally once daily for another 28 weeks in this LTE study.

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

Dosage and administration details:

Subjects received Fesoterodine 8 mg PR tablet orally once daily for 28 weeks in this study.

Arm title	Fesoterodine 2 mg Capsule

Arm description:

In precedent study A0220147, subjects of cohort 2, with body weight less than or equal to (<=) 25 kg, received fesoterodine 2 mg beads-in-capsule (BIC) capsules orally once daily for 24 weeks (12 weeks in each efficacy and safety extension phase). Only Japanese subjects who consented to continue in this LTE study, were to receive fesoterodine 2 mg BIC capsules orally once daily for another 28 weeks in this LTE study.

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

Dosage and administration details:

Subjects received fesoterodine 2 mg BIC capsules orally once daily for 24 weeks in precedent study A0221047 and received fesoterodine 2 mg BIC capsules orally once daily for another 28 weeks in this study.

Arm title	Fesoterodine 4 mg Capsule

Arm description:

In precedent study A0221047, subjects of cohort 2, with body weight <=25 kg, received fesoterodine 2 mg BIC capsules orally once daily for 1 week and if well tolerated then fesoterodine 4 mg BIC capsules orally once daily for 11 weeks in efficacy phase and 12 weeks in safety extension phase. Only Japanese subjects who consented to continue in this LTE study, were to receive fesoterodine 4 mg BIC capsules orally once daily for another 28 weeks in this LTE study.

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

Dosage and administration details:

Subjects received fesoterodine 2 mg BIC capsules orally once daily for 1 week and if well tolerated then fesoterodine 4 mg BIC capsules orally once daily for 11 weeks (in active comparator phase) and 12 weeks (in safety extension phase) in precedent study A0220147 and received fesoterodine 4 mg BIC capsules orally once daily for another 28 weeks in this LTE study.

Number of subjects in period 1	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule
Started	2	7	3
Completed	2	6	3
Not completed	0	1	0
Withdrawal By Parent/Guardian	-	1	-

Baseline characteristics

Reporting groups	
Reporting group title	Fesoterodine 8 mg Tablet
Reporting group description:	
In precedent study A0221047, subject of cohort 1, with body weight greater than (>) 25 kilogram (kg), received fesoterodine 4 milligram (mg) prolonged release (PR) tablet once daily for 1 week and if well tolerated then fesoterodine 8 mg PR tablet once daily for 11 weeks in active comparator phase and 12 weeks in safety extension phase. Only Japanese subject who consented to continue in this LTE study, were to receive fesoterodine 8 mg PR tablet orally once daily for another 28 weeks in this LTE study.	
Reporting group title	Fesoterodine 2 mg Capsule
Reporting group description:	
In precedent study A0220147, subjects of cohort 2, with body weight less than or equal to (<=) 25 kg, received fesoterodine 2 mg beads-in-capsule (BIC) capsules orally once daily for 24 weeks (12 weeks in each efficacy and safety extension phase). Only Japanese subjects who consented to continue in this LTE study, were to receive fesoterodine 2 mg BIC capsules orally once daily for another 28 weeks in this LTE study.	
Reporting group title	Fesoterodine 4 mg Capsule
Reporting group description:	
In precedent study A0221047, subjects of cohort 2, with body weight <=25 kg, received fesoterodine 2 mg BIC capsules orally once daily for 1 week and if well tolerated then fesoterodine 4 mg BIC capsules orally once daily for 11 weeks in efficacy phase and 12 weeks in safety extension phase. Only Japanese subjects who consented to continue in this LTE study, were to receive fesoterodine 4 mg BIC capsules orally once daily for another 28 weeks in this LTE study.	

Reporting group values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule
Number of subjects	2	7	3
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	7	3
Adolescents (12-17 years)	2	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean	13.50	7.86	7.33
standard deviation	± 0.71	± 1.68	± 0.58
Sex: Female, Male Units: subjects			
Female	2	0	1
Male	0	7	2
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	2	7	3

Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	0	0	0
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	2	7	3
Unknown or Not Reported	0	0	0

Reporting group values	Total		
Number of subjects	12		
Age categorical			
Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	10		
Adolescents (12-17 years)	2		
Adults (18-64 years)	0		
From 65-84 years	0		
85 years and over	0		
Age Continuous			
Units: years			
arithmetic mean			
standard deviation	-		
Sex: Female, Male			
Units: subjects			
Female	3		
Male	9		
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0		
Asian	12		
Native Hawaiian or Other Pacific Islander	0		
Black or African American	0		
White	0		
More than one race	0		
Unknown or Not Reported	0		
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0		
Not Hispanic or Latino	12		
Unknown or Not Reported	0		

End points

End points reporting groups

Reporting group title	Fesoterodine 8 mg Tablet

Reporting group description:

In precedent study A0221047, subject of cohort 1, with body weight greater than (>) 25 kilogram (kg), received fesoterodine 4 milligram (mg) prolonged release (PR) tablet once daily for 1 week and if well tolerated then fesoterodine 8 mg PR tablet once daily for 11 weeks in active comparator phase and 12 weeks in safety extension phase. Only Japanese subject who consented to continue in this LTE study, were to receive fesoterodine 8 mg PR tablet orally once daily for another 28 weeks in this LTE study.

Reporting group title	Fesoterodine 2 mg Capsule

Reporting group description:

In precedent study A0220147, subjects of cohort 2, with body weight less than or equal to (<=) 25 kg, received fesoterodine 2 mg beads-in-capsule (BIC) capsules orally once daily for 24 weeks (12 weeks in each efficacy and safety extension phase). Only Japanese subjects who consented to continue in this LTE study, were to receive fesoterodine 2 mg BIC capsules orally once daily for another 28 weeks in this LTE study.

Reporting group title	Fesoterodine 4 mg Capsule

Reporting group description:

In precedent study A0221047, subjects of cohort 2, with body weight <=25 kg, received fesoterodine 2 mg BIC capsules orally once daily for 1 week and if well tolerated then fesoterodine 4 mg BIC capsules orally once daily for 11 weeks in efficacy phase and 12 weeks in safety extension phase. Only Japanese subjects who consented to continue in this LTE study, were to receive fesoterodine 4 mg BIC capsules orally once daily for another 28 weeks in this LTE study.

Subject analysis set title	Cohort 1
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects of cohort 1 with body weight >25 kg, who received fesoterodine 4 mg or 8 mg PR tablet orally once daily for 24 weeks (12 weeks in each active comparator and safety extension phase) in precedent study A0221047 and then continued same dose and dosage form of fesoterodine for 28 weeks in this LTE study.

Subject analysis set title	Cohort 2
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects of cohort 2 with body weight <=25 kg, who received either fesoterodine 2 mg or 4 mg capsule orally once daily in efficacy and safety phase in precedent study A0221047 and then continued same dose and dosage form of fesoterodine for 28 weeks in this LTE study.

Subject analysis set title	Total of Treatment Groups
Subject analysis set type	Full analysis

Subject analysis set description:

Total Subjects who received fesoterodine 8 mg PR tablet, fesoterodine 2 mg and 4 mg BIC capsules in precedent study A0221047 and continued to receive same treatment respectively, in this LTE study.

Primary: Number of Subjects With Treatment Emergent Adverse Events (AEs) and Serious Adverse Events (SAEs): Merged Data of Studies A0221047 and A0221109

End point title	Number of Subjects With Treatment Emergent Adverse Events (AEs) and Serious Adverse Events (SAEs): Merged Data of Studies A0221047 and A0221109[1]

End point description:

An AE was any untoward medical occurrence in 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 hospitalization;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 treatment period that was absent before treatment, or worsened during treatment period relative to pretreatment state. AEs included both serious and non-serious adverse events. TEAEs were summarized for each cohort (Cohort 1 and Cohort 2, irrespective of treatment received), each treatment group and the total of treatment groups, using the merged data of studies A0221047 and A0221109 as planned. Safety analysis set was analyzed.

End point type	Primary

End point timeframe:

Up to a maximum of 56 weeks (24 weeks of treatment in A0221047 and 32 weeks [28 weeks treatment + 4 weeks follow up post last dose] in A0221109)

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: No statistical analysis was planned for this endpoint

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	Cohort 1
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	2	7	3	2
Units: subjects				
Subjects with AEs	2	6	3	2
Subjects with SAEs	0	1	0	0

End point values	Cohort 2	Total of Treatment Groups		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	10	12		
Units: subjects				
Subjects with AEs	9	11		
Subjects with SAEs	1	1		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Visual Acuity at Week 12: Study A0221109

End point title	Change From Baseline in Visual Acuity at Week 12: Study A0221109[2]

End point description:

Visual acuity (VA) was assessed for each eye 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 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. Data for this endpoint was planned to be analyzed for each treatment group of study A0221109 only. Safety analysis set included all subjects who were enrolled and received at least one dose of study medication in study A0221109.

End point type	Primary

End point timeframe:

A0221109: Baseline, Week 12

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: No statistical analysis was planned for this endpoint

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	7	3	
Units: LogMAR				
arithmetic mean (standard deviation)				
Right Eye: Baseline	0.27 (± 0.376)	0.04 (± 0.137)	0.28 (± 0.334)	
Right Eye: Change at Week 12	0.14 (± 0.204)	-0.03 (± 0.083)	0.04 (± 0.067)	
Left Eye: Baseline	0.45 (± 0.350)	0.04 (± 0.183)	0.63 (± 0.663)	
Left Eye: Change at Week 12	0.03 (± 0.126)	0.03 (± 0.116)	0.07 (± 0.122)	

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Visual Acuity at Week 28: Study A0221109

End point title	Change From Baseline in Visual Acuity at Week 28: Study A0221109[3]

End point description:

VA was assessed for each eye 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. Data for this endpoint was planned to be analyzed for each treatment group of study A0221109 only. Safety analysis set included all subjects who were enrolled and received at least one dose of study medication in study A0221109. Here, 'Number of subjects analysed' = subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

A0221109: Baseline, Week 28

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: No statistical analysis was planned for this endpoint

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	6	3	
Units: LogMAR				
arithmetic mean (standard deviation)				
Right Eye	0.00 (± 0.000)	0.03 (± 0.118)	0.02 (± 0.142)	
Left Eye	0.31 (± 0.681)	0.05 (± 0.057)	0.16 (± 0.208)	

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Visual Acuity at Final Visit: Study A0221109

End point title	Change From Baseline in Visual Acuity at Final Visit: Study A0221109[4]

End point description:

VA was assessed for each eye 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. Data for this endpoint was planned to be analysed for each treatment group of study A0221109 only. Safety analysis set included all subjects who were enrolled and received at least one dose of study medication in study A0221109.

End point type	Primary

End point timeframe:

A0221109: Baseline, Final visit (Week 28 for subjects who completed the study or in case of early withdrawal the last assessment before Week 28 was considered to be the final visit)

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: No statistical analysis was planned for this endpoint

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	7	3	
Units: LogMAR				
arithmetic mean (standard deviation)				
Right Eye	0.00 (± 0.000)	0.02 (± 0.108)	0.02 (± 0.142)	
Left Eye	0.31 (± 0.681)	0.04 (± 0.055)	0.16 (± 0.208)	

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Visual Accommodation at Week 12: Study A0221109

End point title	Change From Baseline in Visual Accommodation at Week 12: Study A0221109[5]

End point description:

The visual accommodation was the minimum focusing 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. Data for this endpoint was planned to be analysed for each treatment group of study A0221109 only. Safety analysis set included all subjects who were enrolled and received at least one dose of study medication in study A0221109. Here, 'n' = subjects evaluable for this endpoint for specified rows.

End point type	Primary

End point timeframe:

A0221109: Baseline, Week 12

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: No statistical analysis was planned for this endpoint

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	7	3	
Units: centimeter				
arithmetic mean (standard deviation)				
Right Eye: Baseline (n =2, 7, 3)	9.33 (± 8.014)	8.62 (± 10.938)	5.56 (± 4.857)	
Right Eye: Change at Week 12 (n =2, 7, 3)	2.50 (± 2.593)	5.86 (± 13.287)	6.67 (± 10.990)	
Left Eye: Baseline (n =2, 7, 2)	14.00 (± 13.199)	9.86 (± 13.685)	4.83 (± 6.835)	
Left Eye: Change at Week 12 (n =2, 7, 2)	-1.83 (± 2.593)	3.24 (± 13.662)	16.17 (± 23.806)	

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Visual Accommodation at Week 28: Study A0221109

End point title	Change From Baseline in Visual Accommodation at Week 28: Study A0221109[6]

End point description:

The visual accommodation was the minimum focusing distance for each eye at which vision became blurred – the mean of triplicate measurements. The subject 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. Data for this endpoint was planned to be analysed for each treatment group of study A0221109 only. Safety analysis set included all subjects who were enrolled and received at least one dose of study medication in study A0221109. Here, 'Number of subjects analysed' = subjects evaluable for this endpoint. Here, 'n' = subjects evaluable for this endpoint for specified rows.

End point type	Primary

End point timeframe:

A0221109: Baseline, Week 28

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: No statistical analysis was planned for this endpoint

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	6	3	
Units: centimeter				
arithmetic mean (standard deviation)				
Right Eye (n =2, 6, 3)	5.17 (± 7.307)	0.78 (± 2.639)	-0.11 (± 1.836)	
Left Eye (n =2, 6, 2)	3.17 (± 5.421)	-0.39 (± 3.803)	0.50 (± 0.707)	

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Visual Accommodation at Final Visit: Study A0221109

End point title	Change From Baseline in Visual Accommodation at Final Visit: Study A0221109[7]

End point description:

The visual accommodation was the minimum focusing distance for each eye at which vision became blurred – the mean of triplicate measurements. The subject 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. Data for this endpoint was planned to be analysed for each treatment group of study A0221109 only. Safety analysis set included all subjects who were enrolled and received at least one dose of study medication in study A0221109. Here, 'n' = subjects evaluable for this endpoint for specified rows.

End point type	Primary

End point timeframe:

A0221109: Baseline, Final visit (Week 28 for subjects who completed the study or in case of early withdrawal the last assessment before Week 28 was considered to be the final visit)

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: No statistical analysis was planned for this endpoint

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	7	3	
Units: centimeter				
arithmetic mean (standard deviation)				
Right Eye (n =2, 7, 3)	5.17 (± 7.307)	4.38 (± 9.833)	-0.11 (± 1.836)	
Left Eye (n =2, 7, 2)	3.17 (± 5.421)	2.86 (± 9.263)	0.50 (± 0.707)	

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Child Behavior Checklist (CBCL) T Score (Derived Score) at Week 12: Study A0221109

End point title	Change From Baseline in Child Behavior Checklist (CBCL) T Score (Derived Score) at Week 12: Study A0221109[8]

End point description:

CBCL: assessed child's behavioral and emotional problems (pbl). Parent/caregiver of child answered 120 items, each on scale: 0=not true, 1=somewhat/sometimes true, 2=very/often true. 103 items were classified in 8 domains: aggressive behavior, total score range (TSR) =0-36; anxious/depressed, TSR=0-26; attention pbl, TSR=0-20; rule-breaking behavior, TSR=0-34; social pbl, TSR=0-22; somatic complaints, TSR=0-22; thought pbl, TSR=0-30; withdrawn, TSR=0-16. Summary scores: externalizing pbl combined rule-breaking and aggressive behavior, TSR=0-70; internalizing pbl combined anxious/depressed, withdrawn and somatic complaints, TSR=0-64. Total pbl combined 8 domains and 17 remaining items, TSR=0-240. TSR for each domain, summary and total pbl was sum of scores of related items respectively. Lower scores for each domain, summary, total pbl = better outcomes. Data for this endpoint was planned to be analyzed for each treatment group of study A0221109. Safety analysis set.

End point type	Primary

End point timeframe:

A0221109: Baseline, Week 12

Notes:

[8] - 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: No statistical analysis was planned for this endpoint

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	7	3	
Units: units on a scale				
arithmetic mean (standard deviation)				
Aggressive behavior: Baseline	50.0 (± 0.00)	52.6 (± 3.82)	50.7 (± 1.15)	
Aggressive behavior: Change at Week 12	0.0 (± 0.00)	-0.1 (± 3.53)	0.0 (± 0.00)	
Anxious/depressed: Baseline	50.0 (± 0.00)	52.1 (± 3.34)	50.7 (± 0.58)	
Anxious/depressed: Change at Week 12	0.0 (± 0.00)	0.7 (± 4.11)	-0.7 (± 0.58)	
Attention problems: Baseline	50.0 (± 0.00)	53.6 (± 3.55)	53.3 (± 4.93)	
Attention problems: Change at week 12	0.0 (± 0.00)	-1.1 (± 2.34)	0.0 (± 0.00)	
Rule-breaking behavior: Baseline	50.5 (± 0.71)	52.4 (± 3.60)	53.3 (± 5.77)	
Rule-breaking behavior: Change at Week 12	0.0 (± 0.00)	-0.3 (± 4.11)	0.0 (± 0.00)	
Social problems: Baseline	50.0 (± 0.00)	52.4 (± 2.70)	54.3 (± 6.66)	
Social problems: Change at Week 12	0.0 (± 0.00)	0.0 (± 3.65)	0.7 (± 1.15)	
Somatic complaints: Baseline	51.5 (± 2.12)	53.4 (± 5.35)	55.7 (± 4.62)	
Somatic complaints: Change at Week 12	1.5 (± 2.12)	0.9 (± 1.46)	-2.3 (± 2.08)	
Thought problems: Baseline	50.0 (± 0.00)	50.9 (± 1.46)	53.0 (± 4.36)	
Thought problems: Change at Week 12	0.0 (± 0.00)	0.3 (± 1.70)	0.0 (± 0.00)	
Withdrawn: Baseline	50.0 (± 0.00)	53.4 (± 4.86)	52.7 (± 4.62)	
Withdrawn: Change at Week 12	0.0 (± 0.00)	-1.7 (± 4.54)	0.0 (± 0.00)	
Externalizing problems: Baseline	37.0 (± 4.24)	47.6 (± 8.79)	44.0 (± 10.00)	
Externalizing problems: Change at Week 12	0.0 (± 0.00)	-0.3 (± 6.07)	0.0 (± 0.00)	
Internalizing problems: Baseline	36.0 (± 4.24)	49.0 (± 3.79)	47.7 (± 7.51)	
Internalizing problems: Change at Week 12	3.0 (± 4.24)	0.4 (± 5.00)	-4.0 (± 2.00)	
Total problems: Baseline	30.5 (± 2.12)	49.1 (± 3.67)	46.7 (± 11.59)	
Total problems: Change at Week 12	3.0 (± 4.24)	-1.1 (± 2.12)	0.3 (± 1.53)	

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Child Behavior Checklist (CBCL) T Score (Derived Score) at Week 28: Study A0221109

End point title	Change From Baseline in Child Behavior Checklist (CBCL) T Score (Derived Score) at Week 28: Study A0221109[9]

End point description:

CBCL:assessed child's behavioral and emotional problems(pbl). Parent/caregiver of child answered 120 items,each on scale:0=not true,1=somewhat/sometimes true,2=very/often true.103 items were classified in 8 domains: aggressive behavior, TSR =0-36; anxious/depressed, TSR=0-26; attention pbl, TSR=0-20; rule-breaking behavior, TSR=0-34; social pbl, TSR=0-22; somatic complaints, TSR=0-22;

thought pbl, TSR=0-30; withdrawn, TSR=0-16. Summary scores: externalizing pbl combined rule-breaking and aggressive behavior, TSR=0-70;internalizing pbl combined anxious/depressed,withdrawn and somatic complaints,TSR=0-64.Total pbl combined 8 domains and 17 remaining items,TSR=0-240.TSR for each domain,summary and total pbl was sum of scores of related items respectively.Lower scores for each domain, summary,total pbl=better outcomes.Data for this endpoint was planned to be analyzed for each treatment group of study A0221109. Safety set. Number of subjects analysed=subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

A0221109: Baseline, Week 28

Notes:

[9] - 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: No statistical analysis was planned for this endpoint

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	6	3	
Units: units on a scale				
arithmetic mean (standard deviation)				
Aggressive behavior	0.0 (± 0.00)	-2.2 (± 3.76)	-0.3 (± 0.58)	
Anxious/depressed	0.0 (± 0.00)	-0.7 (± 4.13)	0.3 (± 1.53)	
Attention problems	0.0 (± 0.00)	-1.0 (± 2.45)	0.0 (± 0.00)	
Rule-breaking behavior	-0.5 (± 0.71)	-1.0 (± 2.97)	1.3 (± 2.31)	
Social problems	0.0 (± 0.00)	0.3 (± 1.63)	1.0 (± 1.73)	
Somatic complaints	0.0 (± 0.00)	1.2 (± 1.83)	-2.3 (± 2.08)	
Thought problems	0.0 (± 0.00)	-0.2 (± 0.41)	-0.3 (± 0.58)	
Withdrawn	0.0 (± 0.00)	-2.0 (± 7.04)	0.0 (± 0.00)	
Externalizing problems	-3.0 (± 4.24)	-3.5 (± 5.92)	0.0 (± 0.00)	
Internalizing problems	0.0 (± 0.00)	-2.5 (± 6.83)	-2.7 (± 3.06)	
Total problems	-2.5 (± 3.54)	-1.7 (± 2.94)	1.0 (± 1.00)	

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Child Behavior Checklist (CBCL) T Score (Derived Score) at Final Visit: Study A0221109

End point title	Change From Baseline in Child Behavior Checklist (CBCL) T Score (Derived Score) at Final Visit: Study A0221109[10]

End point description:

CBCL: assessed child's behavioral and emotional problems (pbl). Parent/caregiver of child answered 120 items, each on scale: 0=not true, 1=somewhat/sometimes true, 2=very/often true. 103 items were classified in 8 domains: aggressive behavior, TSR =0-36; anxious/depressed, TSR=0-26; attention pbl, TSR=0-20; rule-breaking behavior, TSR=0-34; social pbl, TSR=0-22; somatic complaints, TSR=0-22; thought pbl, TSR=0-30; withdrawn, TSR=0-16. Summary scores: externalizing pbl combined rule-breaking and aggressive behavior, TSR=0-70; internalizing pbl combined anxious/depressed, withdrawn and somatic complaints, TSR=0-64. Total pbl combined 8 domains and 17 remaining items, TSR=0-240. TSR for each domain, summary and total pbl was sum of scores of related items respectively. Lower scores for each domain, summary, total pbl = better outcomes. Data for this endpoint was planned to be analyzed for each treatment group of study A0221109. Safety analysis set.

End point type	Primary

End point timeframe:

A0221109: Baseline, Final visit (Week 28 for subjects who completed the study or in case of early withdrawal the last assessment before Week 28 was considered to be the final visit)

Notes:

[10] - 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: No statistical analysis was planned for this endpoint

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	7	3	
Units: units on a scale				
arithmetic mean (standard deviation)				
Aggressive behavior	0.0 (± 0.00)	-1.9 (± 3.53)	-0.3 (± 0.58)	
Anxious/depressed	0.0 (± 0.00)	-0.6 (± 3.78)	0.3 (± 1.53)	
Attention problems	0.0 (± 0.00)	-0.9 (± 2.27)	0.0 (± 0.00)	
Rule-breaking behavior	-0.5 (± 0.71)	-0.9 (± 2.73)	1.3 (± 2.31)	
Social problems	0.0 (± 0.00)	0.3 (± 1.50)	1.0 (± 1.73)	
Somatic complaints	0.0 (± 0.00)	1.0 (± 1.73)	-2.3 (± 2.08)	
Thought problems	0.0 (± 0.00)	-0.1 (± 0.38)	-0.3 (± 0.58)	
Withdrawn	0.0 (± 0.00)	-1.7 (± 6.47)	0.0 (± 0.00)	
Externalizing problems	-3.0 (± 4.24)	-3.0 (± 5.57)	0.0 (± 0.00)	
Internalizing problems	0.0 (± 0.00)	-2.1 (± 6.31)	-2.7 (± 3.06)	
Total problems	-2.5 (± 3.54)	-1.4 (± 2.76)	1.0 (± 1.00)	

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Child Behavior Checklist (CBCL) Total Score (Raw Score) at Week 12: Study A0221109

End point title	Change From Baseline in Child Behavior Checklist (CBCL) Total Score (Raw Score) at Week 12: Study A0221109[11]

End point description:

CBCL: assessed child's behavioral and emotional problems (pbl). Parent/caregiver of child answered 120 items, each on scale: 0=not true, 1=somewhat/sometimes true, 2=very/often true. 103 items were classified in 8 domains: aggressive behavior, TSR =0-36; anxious/depressed, TSR=0-26; attention pbl, TSR=0-20; rule-breaking behavior, TSR=0-34; social pbl, TSR=0-22; somatic complaints, TSR=0-22; thought pbl, TSR=0-30; withdrawn, TSR=0-16. Summary scores: externalizing pbl combined rule-breaking and aggressive behavior, TSR=0-70; internalizing pbl combined anxious/depressed, withdrawn and somatic complaints, TSR=0-64. Total pbl combined 8 domains and 17 remaining items, TSR=0-240. TSR for each domain, summary and total pbl was sum of scores of related items respectively. Lower scores for each domain, summary, total pbl = better outcomes. Data for this endpoint was planned to be analyzed for each treatment group of study A0221109. Safety analysis set.

End point type	Primary

End point timeframe:

A0221109: Baseline, Week 12

Notes:

[11] - 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: No statistical analysis was planned for this endpoint

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	7	3	
Units: units on a scale				
arithmetic mean (standard deviation)				
Aggressive behavior: Baseline	0.0 (± 0.00)	3.4 (± 3.05)	2.0 (± 2.00)	
Aggressive behavior: Change at Week 12	0.0 (± 0.00)	-0.1 (± 2.97)	0.0 (± 0.00)	
Anxious/depressed: Baseline	0.0 (± 0.00)	1.9 (± 1.57)	1.3 (± 1.15)	
Anxious/depressed: Change at Week 12	0.0 (± 0.00)	0.3 (± 1.60)	-0.7 (± 0.58)	
Attention problems: Baseline	0.0 (± 0.00)	3.6 (± 2.64)	3.0 (± 3.46)	
Attention problems: Change at week 12	0.0 (± 0.00)	-0.6 (± 1.27)	0.0 (± 0.00)	
Rule-breaking behavior: Baseline	0.5 (± 0.71)	1.3 (± 1.50)	1.3 (± 2.31)	
Rule-breaking behavior: Change at Week 12	0.0 (± 0.00)	-0.1 (± 1.21)	0.0 (± 0.00)	
Social problems: Baseline	0.0 (± 0.00)	1.6 (± 1.27)	2.3 (± 3.21)	
Social problems: Change at Week 12	0.0 (± 0.00)	0.0 (± 1.63)	0.3 (± 0.58)	
Somatic complaints: Baseline	0.5 (± 0.71)	1.0 (± 1.53)	1.7 (± 1.15)	
Somatic complaints: Change at Week 12	0.5 (± 0.71)	0.3 (± 0.49)	-0.7 (± 0.58)	
Thought problems: Baseline	0.0 (± 0.00)	0.6 (± 0.79)	1.3 (± 1.53)	
Thought problems: Change at Week 12	0.0 (± 0.00)	-0.1 (± 0.69)	0.0 (± 0.00)	
Withdrawn: Baseline	0.0 (± 0.00)	0.9 (± 1.21)	0.7 (± 1.15)	
Withdrawn: Change at Week 12	0.0 (± 0.00)	-0.4 (± 1.13)	0.0 (± 0.00)	
Externalizing: Baseline	0.5 (± 0.71)	4.7 (± 4.27)	3.3 (± 4.16)	
Externalizing: Change at Week 12	0.0 (± 0.00)	-0.3 (± 3.59)	0.0 (± 0.00)	
Internalizing: Baseline	0.5 (± 0.71)	3.7 (± 1.38)	3.7 (± 2.31)	
Internalizing: Change at Week 12	0.5 (± 0.71)	0.1 (± 2.19)	-1.3 (± 0.58)	
Total problems: Baseline	1.5 (± 0.71)	19.1 (± 5.79)	18.0 (± 17.78)	
Total problems: Change at Week 12	1.0 (± 1.41)	-1.3 (± 4.07)	-0.3 (± 1.15)	

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Child Behavior Checklist (CBCL) Total Score (Raw Score) at Week 28: Study A0221109

End point title	Change From Baseline in Child Behavior Checklist (CBCL) Total Score (Raw Score) at Week 28: Study A0221109[12]

End point description:

CBCL: assessed child's behavioral and emotional (pbl).Parent/caregiver of child answered 120 items, each on scale: 0=not true, 1=somewhat/sometimes true, 2=very/often true. 103 items were classified in 8 domains: aggressive behavior,TSR =0-36;anxious/depressed,TSR=0-26;attention pbl,TSR=0-20;rule-breaking behavior,TSR=0-34;social pbl,TSR=0-22;somatic complaints,TSR=0-22;thought pbl,TSR=0-30;withdrawn,TSR=0-16.Summary scores: externalizing pbl combined rule-breaking and aggressive behavior, TSR=0-70; internalizing pbl combined anxious/depressed, withdrawn and somatic complaints, TSR=0-64. Total pbl combined 8 domains and 17 remaining items, TSR=0-240. TSR for each domain, summary and total pbl was sum of scores of related items respectively. Lower scores for each domain, summary, total pbl = better outcomes. Data for this endpoint was planned to be analyzed for each treatment group of study A0221109. Safety analysis set. Number of subjects analysed=subjects evaluable for the endpoint

End point type	Primary

End point timeframe:

A0221109: Baseline, Week 28

Notes:

[12] - 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: No statistical analysis was planned for this endpoint

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	6	3	
Units: units on a scale				
arithmetic mean (standard deviation)				
Aggressive behavior	0.0 (± 0.00)	-1.8 (± 3.06)	-0.3 (± 0.58)	
Anxious/depressed	0.0 (± 0.00)	-0.3 (± 1.37)	0.0 (± 1.00)	
Attention problems	0.0 (± 0.00)	-0.5 (± 1.22)	0.0 (± 0.00)	
Rule-breaking behavior	-0.5 (± 0.71)	-0.2 (± 0.98)	0.3 (± 0.58)	
Social problems	0.0 (± 0.00)	0.2 (± 0.98)	0.3 (± 0.58)	
Somatic complaints	0.0 (± 0.00)	0.3 (± 0.52)	-0.7 (± 0.58)	
Thought problems	0.0 (± 0.00)	-0.2 (± 0.41)	-0.3 (± 0.58)	
Withdrawn	0.0 (± 0.00)	-0.5 (± 1.76)	0.0 (± 0.00)	
Externalizing	-0.5 (± 0.71)	-2.0 (± 3.58)	0.0 (± 0.00)	
Internalizing	0.0 (± 0.00)	-0.5 (± 2.88)	-0.7 (± 0.58)	
Total problems	-0.5 (± 0.71)	-2.7 (± 4.63)	0.7 (± 0.58)	

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Child Behavior Checklist (CBCL) Total Score (Raw Score) at Final Visit: Study A0221109

End point title	Change From Baseline in Child Behavior Checklist (CBCL) Total Score (Raw Score) at Final Visit: Study A0221109[13]

End point description:

CBCL: assessed child's behavioral and emotional problems (pbl). Parent/caregiver of child answered 120 items, each on scale: 0=not true, 1=somewhat/sometimes true, 2=very/often true. 103 items were classified in 8 domains: aggressive behavior, TSR =0-36; anxious/depressed, TSR=0-26; attention pbl, TSR=0-20; rule-breaking behavior, TSR=0-34; social pbl, TSR=0-22; somatic complaints, TSR=0-22; thought pbl, TSR=0-30; withdrawn, TSR=0-16. Summary scores: externalizing pbl combined rule-breaking and aggressive behavior, TSR=0-70; internalizing pbl combined anxious/depressed, withdrawn and somatic complaints, TSR=0-64. Total pbl combined 8 domains and 17 remaining items, TSR=0-240. TSR for each domain, summary and total pbl was sum of scores of related items respectively. Lower scores for each domain, summary, total pbl = better outcomes. Data for this endpoint was planned to be analyzed for each treatment group of study A0221109. Safety analysis set.

End point type	Primary

End point timeframe:

A0221109: Baseline, Final visit (Week 28 for subjects who completed the study or in case of early withdrawal the last assessment before Week 28 was considered to be the final visit)

Notes:

[13] - 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: No statistical analysis was planned for this endpoint

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	7	3	
Units: units on a scale				
arithmetic mean (standard deviation)				
Aggressive behavior	0.0 (± 0.00)	-1.6 (± 2.88)	-0.3 (± 0.58)	
Anxious/depressed	0.0 (± 0.00)	-0.3 (± 1.25)	0.0 (± 1.00)	
Attention problems	0.0 (± 0.00)	-0.4 (± 1.13)	0.0 (± 0.00)	
Rule-breaking behavior	-0.5 (± 0.71)	-0.1 (± 0.90)	0.3 (± 0.58)	
Social problems	0.0 (± 0.00)	0.1 (± 0.90)	0.3 (± 0.58)	
Somatic complaints	0.0 (± 0.00)	0.3 (± 0.49)	-0.7 (± 0.58)	
Thought problems	0.0 (± 0.00)	-0.1 (± 0.38)	-0.3 (± 0.58)	
Withdrawn	0.0 (± 0.00)	-0.4 (± 1.62)	0.0 (± 0.00)	
Externalizing	-0.5 (± 0.71)	-1.7 (± 3.35)	0.0 (± 0.00)	
Internalizing	0.0 (± 0.00)	-0.4 (± 2.64)	-0.7 (± 0.58)	
Total problems	-0.5 (± 0.71)	-2.3 (± 4.35)	0.7 (± 0.58)	

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Grooved Pegboard Test (10 Pegs Group) at Week 12- Time to Completion: Study A0221109

End point title	Change From Baseline in Grooved Pegboard Test (10 Pegs Group) at Week 12- Time to Completion: Study A0221109[14]

End point description:

The grooved pegboard test was a manipulative dexterity test that assessed psychomotor speed, fine motor control, and rapid-visual motor coordination. Subjects were asked to insert 10 grooved pegs into 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. In this endpoint data for dominant and non-dominant hand have been reported separately. Data for this endpoint was planned to be analysed for each treatment group of study A0221109 only. Safety analysis set included all subjects who were enrolled and received at least one dose of study medication in study A0221109. Here, 'Number of subjects analysed' = subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

A0221109: Baseline, Week 12

Notes:

[14] - 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: No statistical analysis was planned for this endpoint

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[15]	5	3	
Units: seconds				
arithmetic mean (standard deviation)				
Dominant hand: Baseline	()	43.0 (± 23.44)	39.3 (± 15.18)	
Dominant hand: Change at Week 12	()	0.8 (± 6.72)	-0.3 (± 15.28)	

Non-dominant hand: Baseline	()	33.4 (± 10.74)	52.0 (± 19.67)	
Non-dominant hand: Change at Week 12	()	8.2 (± 19.93)	-1.3 (± 9.45)	

Notes:

[15] - No subject was of age below 9 years.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Grooved Pegboard Test (10 Pegs Group) at Week 28- Time to Completion: Study A0221109

End point title	Change From Baseline in Grooved Pegboard Test (10 Pegs Group) at Week 28- Time to Completion: Study A0221109[16]

End point description:

The grooved pegboard test was a manipulative dexterity test that assessed psychomotor speed, fine motor control, and rapid-visual motor coordination. Subjects were asked to insert 10 grooved pegs into 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. In this endpoint data for dominant and non-dominant hand have been reported separately. Data for this endpoint was planned to be analysed for each treatment group of study A0221109 only. Safety analysis set included all subjects who were enrolled and received at least one dose of study medication in study A0221109. Here, 'Number of subjects analysed' = subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

A0221109: Baseline, Week 28

Notes:

[16] - 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: No statistical analysis was planned for this endpoint

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[17]	4	3	
Units: seconds				
arithmetic mean (standard deviation)				
Dominant hand	()	4.5 (± 2.38)	3.7 (± 4.04)	
Non-dominant hand	()	6.3 (± 7.37)	-7.7 (± 10.26)	

Notes:

[17] - No subject was of age below 9 years.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Grooved Pegboard Test (10 Pegs Group) at Final Visit- Time to Completion: Study A0221109

End point title	Change From Baseline in Grooved Pegboard Test (10 Pegs Group) at Final Visit- Time to Completion: Study A0221109[18]

End point description:

The grooved pegboard test was a manipulative dexterity test that assessed psychomotor speed, fine motor control, and rapid-visual motor coordination. Subjects were asked to insert 10 grooved pegs into

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. In this endpoint data for dominant and non-dominant hand have been reported separately. Data for this endpoint was planned to be analysed for each treatment group of Study A0221109 only. Safety analysis set included all subjects who were enrolled and received at least one dose of study medication in Study A0221109. Here, 'Number of subjects analysed' = subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

A0221109: Baseline, Final visit (Week 28 for subjects who completed the study or in case of early withdrawal the last assessment before Week 28 was considered to be the final visit)

Notes:

[18] - 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: No statistical analysis was planned for this endpoint

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[19]	5	3	
Units: seconds				
arithmetic mean (standard deviation)				
Dominant hand	()	0.8 (± 8.53)	3.7 (± 4.04)	
Non-dominant hand	()	4.4 (± 7.60)	-7.7 (± 10.26)	

Notes:

[19] - No subject was of age below 9 years.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Grooved Pegboard Test (25 Pegs Group) at Week 12- Time to Completion: Study A0221109

End point title	Change From Baseline in Grooved Pegboard Test (25 Pegs Group) at Week 12- Time to Completion: Study A0221109[20]

End point description:

The grooved pegboard test was a manipulative dexterity test that assessed psychomotor speed, fine motor control, and rapid-visual motor coordination. Subjects were asked to insert 25 grooved pegs into 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. In this endpoint data for dominant and non-dominant hand have been reported separately. Data for this endpoint was planned to be analysed for each treatment group of Study A0221109 only. Safety analysis set included all subjects who were enrolled and received at least one dose of study medication in Study A0221109. Here, 'Number of subjects analysed' = subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

A0221109: Baseline, Week 12

Notes:

[20] - 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: No statistical analysis was planned for this endpoint

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	2	0[21]	
Units: seconds				
arithmetic mean (standard deviation)				
Dominant hand: Baseline	59.5 (± 6.36)	107.5 (± 75.66)	()	
Dominant hand: Change at Week 12	0.0 (± 2.83)	-11.5 (± 13.44)	()	
Non-dominant hand: Baseline	60.5 (± 6.36)	145.5 (± 132.23)	()	
Non-dominant hand: Change at Week 12	-0.5 (± 4.95)	-2.0 (± 9.90)	()	

Notes:

[21] - No subjects were of age >=9 years.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Grooved Pegboard Test (25 Pegs Group) at Week 28- Time to Completion: Study A0221109

End point title	Change From Baseline in Grooved Pegboard Test (25 Pegs Group) at Week 28- Time to Completion: Study A0221109[22]

End point description:

The grooved pegboard test was a manipulative dexterity test that assessed psychomotor speed, fine motor control, and rapid-visual motor coordination. 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. In this endpoint data for dominant and non-dominant hand have been reported separately. Data for this endpoint was planned to be analysed for each treatment group of study A0221109 only. Safety analysis set included all subjects who were enrolled and received at least one dose of study medication in study A0221109. Here, 'Number of subjects analysed' = subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

A0221109: Baseline, Week 28

Notes:

[22] - 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: No statistical analysis was planned for this endpoint

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	2	0[23]	
Units: seconds				
arithmetic mean (standard deviation)				
Dominant hand	2.0 (± 7.07)	-14.0 (± 24.04)	()	
Non-dominant hand	-1.0 (± 2.83)	-35.0 (± 48.08)	()	

Notes:

[23] - No subject was of age 9 years and above.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Grooved Pegboard Test (25 Pegs Group) at Final Visit- Time to Completion: Study A0221109

End point title	Change From Baseline in Grooved Pegboard Test (25 Pegs Group) at Final Visit- Time to Completion: Study A0221109[24]

End point description:

The grooved pegboard test was a manipulative dexterity test that assessed psychomotor speed, fine motor control, and rapid-visual motor coordination. 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. In this endpoint data for dominant and non-dominant hand have been reported separately. Data for this endpoint was planned to be analysed for each treatment group of study A0221109 only. Safety analysis set included all subjects who were enrolled and received at least one dose of study medication in study A0221109. Here, 'Number of subjects analysed' = subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

A0221109: Baseline, final visit (Week 28 for subjects who completed the study or in case of early withdrawal the last assessment before Week 28 was considered to be the final visit)

Notes:

[24] - 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: No statistical analysis was planned for this endpoint

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	2	0[25]	
Units: seconds				
arithmetic mean (standard deviation)				
Dominant hand	2.08 (± 7.07)	-14.0 (± 24.04)	()	
Non-dominant hand	-1.0 (± 2.83)	-35.0 (± 48.08)	()	

Notes:

[25] - No subject was of age 9 years and above.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Grooved Pegboard Test (10 Pegs Group) at Week 12- Number of Pegs Dropped: Study A0221109

End point title	Change From Baseline in Grooved Pegboard Test (10 Pegs Group) at Week 12- Number of Pegs Dropped: Study A0221109[26]

End point description:

The grooved pegboard test was a manipulative dexterity test that assessed psychomotor speed, fine motor control, and rapid-visual motor coordination. 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. In this endpoint data for dominant and non-dominant hand have been reported separately. Data for this endpoint was planned to be analysed for each treatment group of study A0221109 only. Safety analysis set included

all subjects who were enrolled and received at least one dose of study medication in study A0221109. Here, 'Number of subjects analysed' = subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

A0221109: Baseline, Week 12

Notes:

[26] - 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: No statistical analysis was planned for this endpoint

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[27]	5	3	
Units: pegs				
arithmetic mean (standard deviation)				
Dominant hand: Baseline	()	0.2 (± 0.45)	0.0 (± 0.00)	
Dominant hand: Change at Week 12	()	0.2 (± 0.45)	0.0 (± 0.00)	
Non-dominant hand: Baseline	()	0.0 (± 0.00)	0.0 (± 0.00)	
Non-dominant hand: Change at Week 12	()	0.6 (± 1.34)	0.0 (± 0.00)	

Notes:

[27] - No subject was of age below 9 years.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Grooved Pegboard Test (10 Pegs Group) at Week 28- Number of Pegs Dropped: Study A0221109

End point title	Change From Baseline in Grooved Pegboard Test (10 Pegs Group) at Week 28- Number of Pegs Dropped: Study A0221109[28]

End point description:

The grooved pegboard test was a manipulative dexterity test that assessed psychomotor speed, fine motor control, and rapid-visual motor coordination. 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. In this endpoint data for dominant and non-dominant hand have been reported separately. Data for this endpoint was planned to be analysed for each treatment group of Study A0221109 only. Safety analysis set included all subjects who were enrolled and received at least one dose of study medication in Study A0221109. Here, 'Number of subjects analysed' = subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

A0221109: Baseline, Week 28

Notes:

[28] - 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: No statistical analysis was planned for this endpoint

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[29]	4	3	
Units: pegs				
arithmetic mean (standard deviation)				
Dominant hand	()	0.3 (± 0.96)	0.0 (± 0.00)	
Non-dominant hand	()	0.0 (± 0.00)	0.0 (± 0.00)	

Notes:

[29] - No subject was of age below 9 years.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Grooved Pegboard Test (10 Pegs Group) at Final Visit- Number of Pegs Dropped: Study A0221109

End point title	Change From Baseline in Grooved Pegboard Test (10 Pegs Group) at Final Visit- Number of Pegs Dropped: Study A0221109[30]

End point description:

The grooved pegboard test was a manipulative dexterity test that assessed psychomotor speed, fine motor control, and rapid-visual motor coordination. 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. In this endpoint data for dominant and non-dominant hand have been reported separately. Data for this endpoint was planned to be analysed for each treatment group of Study A0221109 only. Safety analysis set included all subjects who were enrolled and received at least one dose of study medication in Study A0221109. Here, 'Number of subjects analysed' = subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

A0221109: Baseline, Final visit (Week 28 for subjects who completed the study or in case of early withdrawal the last assessment before Week 28 was considered to be the final visit)

Notes:

[30] - 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: No statistical analysis was planned for this endpoint

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[31]	5	3	
Units: pegs				
arithmetic mean (standard deviation)				
Dominant hand	()	0.2 (± 0.84)	0.0 (± 0.00)	
Non-dominant hand	()	0.0 (± 0.00)	0.0 (± 0.00)	

Notes:

[31] - No subject was of age below 9 years.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Grooved Pegboard Test (25 Pegs Group) at Week 12- Number of Pegs Dropped: Study A0221109

End point title	Change From Baseline in Grooved Pegboard Test (25 Pegs Group) at Week 12- Number of Pegs Dropped: Study A0221109[32]

End point description:

The grooved pegboard test was a manipulative dexterity test that assessed psychomotor speed, fine motor control, and rapid-visual motor coordination. 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. In this endpoint data for dominant and non-dominant hand have been reported separately. Data for this endpoint was planned to be analysed for each treatment group of study A0221109 only. Safety analysis set included all subjects who were enrolled and received at least one dose of study medication in study A0221109. Here, 'Number of subjects analysed' = subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

A0221109: Baseline, Week 12

Notes:

[32] - 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: No statistical analysis was planned for this endpoint

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	2	0[33]	
Units: pegs				
arithmetic mean (standard deviation)				
Dominant hand: Baseline	0.0 (± 0.00)	0.5 (± 0.71)	()	
Dominant hand: Change at Week 12	0.0 (± 0.00)	-0.5 (± 0.71)	()	
Non-dominant hand: Baseline	0.0 (± 0.00)	0.5 (± 0.71)	()	
Non-dominant hand: Change at Week 12	0.0 (± 0.00)	-0.5 (± 0.71)	()	

Notes:

[33] - No subject was of age 9 years and above.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Grooved Pegboard Test (25 Pegs Group) at Week 28- Number of Pegs Dropped: Study A0221109

End point title	Change From Baseline in Grooved Pegboard Test (25 Pegs Group) at Week 28- Number of Pegs Dropped: Study A0221109[34]

End point description:

The grooved pegboard test was a manipulative dexterity test that assessed psychomotor speed, fine motor control, and rapid-visual motor coordination. 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. In this endpoint data for dominant and non-dominant hand have been reported separately. Data for this endpoint was planned to be analysed for each treatment group of study A0221109 only. Safety analysis set included all subjects who were enrolled and received at least one dose of study medication in study A0221109. Here, 'Number of subjects analysed' = subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

A0221109: Baseline, Week 28

Notes:

[34] - 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: No statistical analysis was planned for this endpoint

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	2	0[35]	
Units: pegs				
arithmetic mean (standard deviation)				
Dominant hand	0.0 (± 0.00)	0.0 (± 1.41)	()	
Non-dominant hand	0.0 (± 0.00)	-0.5 (± 0.71)	()	

Notes:

[35] - No subject was of age 9 years and above.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Grooved Pegboard Test (25 Pegs Group) at Final Visit- Number of Pegs Dropped: Study A0221109

End point title	Change From Baseline in Grooved Pegboard Test (25 Pegs Group) at Final Visit- Number of Pegs Dropped: Study A0221109[36]

End point description:

The grooved pegboard test was a manipulative dexterity test that assessed psychomotor speed, fine motor control, and rapid-visual motor coordination. 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. In this endpoint data for dominant and non-dominant hand have been reported separately. Data for this endpoint was planned to be analysed for each treatment group of study A0221109 only. Safety analysis set included all subjects who were enrolled and received at least one dose of study medication in study A0221109. Here, 'Number of subjects analysed' = subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

A0221109: Baseline, Final visit (Week 28 for subjects who completed the study or in case of early withdrawal the last assessment before Week 28 was considered to be the final visit)

Notes:

[36] - 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: No statistical analysis was planned for this endpoint

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	2	0[37]	
Units: pegs				
arithmetic mean (standard deviation)				
Dominant hand	0.0 (± 0.00)	0.0 (± 1.41)	()	
Non-dominant hand	0.0 (± 0.00)	-0.5 (± 0.71)	()	

Notes:

[37] - No subject was of age 9 years and above.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Grooved Pegboard Test (10 Pegs Group) at Week 12- Number of Pegs Placed Correctly: Study A0221109

End point title	Change From Baseline in Grooved Pegboard Test (10 Pegs Group) at Week 12- Number of Pegs Placed Correctly: Study A0221109[38]

End point description:

The grooved pegboard test was a manipulative dexterity test that assessed psychomotor speed, fine motor control, and rapid-visual motor coordination. 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. In this endpoint data for dominant and non-dominant hand have been reported separately. Data for this endpoint was planned to be analysed for each treatment group of study A0221109 only. Safety analysis set included all subjects who were enrolled and received at least one dose of study medication in study A0221109. Here, 'Number of subjects analysed' = subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

A0221109: Baseline, Week 12

Notes:

[38] - 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: No statistical analysis was planned for this endpoint

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[39]	5	3	
Units: pegs				
arithmetic mean (standard deviation)				
Dominant hand: Baseline	()	10.0 (± 0.00)	10.0 (± 0.00)	
Dominant hand: Change at Week 12	()	0.0 (± 0.00)	0.0 (± 0.00)	
Non-dominant hand: Baseline	()	10.0 (± 0.00)	10.0 (± 0.00)	
Non-dominant hand: Change at Week 12	()	0.0 (± 0.00)	0.0 (± 0.00)	

Notes:

[39] - No subject was of age below 9 years.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Grooved Pegboard Test (10 Pegs Group) at Week 28- Number of Pegs Placed Correctly: Study A0221109

End point title	Change From Baseline in Grooved Pegboard Test (10 Pegs

	Group) at Week 28- Number of Pegs Placed Correctly: Study A0221109[40]

End point description:

The grooved pegboard test was a manipulative dexterity test that assessed psychomotor speed, fine motor control, and rapid-visual motor coordination. 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. In this endpoint data for dominant and non-dominant hand have been reported separately. Data for this endpoint was planned to be analysed for each treatment group of study A0221109 only. Safety analysis set included all subjects who were enrolled and received at least one dose of study medication in study A0221109. Here, 'Number of subjects analysed' = subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

A0221109: Baseline, Week 28

Notes:

[40] - 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: No statistical analysis was planned for this endpoint

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[41]	4	3	
Units: pegs				
arithmetic mean (standard deviation)				
Dominant hand	()	0.0 (± 0.00)	0.0 (± 0.00)	
Non-dominant hand	()	0.0 (± 0.00)	0.0 (± 0.00)	

Notes:

[41] - No subject was of age below 9 years.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Grooved Pegboard Test (10 Pegs Group) at Final Visit- Number of Pegs Placed Correctly: Study A0221109

End point title	Change From Baseline in Grooved Pegboard Test (10 Pegs Group) at Final Visit- Number of Pegs Placed Correctly: Study A0221109[42]

End point description:

The grooved pegboard test was a manipulative dexterity test that assessed psychomotor speed, fine motor control, and rapid-visual motor coordination. 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. In this endpoint data for dominant and non-dominant hand have been reported separately. Data for this endpoint was planned to be analysed for each treatment group of study A0221109 only. Safety analysis set included all subjects who were enrolled and received at least one dose of study medication in study A0221109. Here, 'Number of subjects analysed' = subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

A0221109: Baseline, Final visit (Week 28 for subjects who completed the study or in case of early withdrawal the last assessment before Week 28 was considered to be the final visit)

Notes:

[42] - 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: No statistical analysis was planned for this endpoint

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[43]	5	3	
Units: pegs				
arithmetic mean (standard deviation)				
Dominant hand	()	0.0 (± 0.00)	0.0 (± 0.00)	
Non-dominant hand	()	0.0 (± 0.00)	0.0 (± 0.00)	

Notes:

[43] - No subjects were of age <9 years.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Grooved Pegboard Test (25 Pegs Group) at Week 12- Number of Pegs Placed Correctly: Study A0221109

End point title	Change From Baseline in Grooved Pegboard Test (25 Pegs Group) at Week 12- Number of Pegs Placed Correctly: Study A0221109[44]

End point description:

The grooved pegboard test was a manipulative dexterity test that assessed psychomotor speed, fine motor control, and rapid-visual motor coordination. 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. In this endpoint data for dominant and non-dominant hand have been reported separately. Data for this endpoint was planned to be analysed for each treatment group of study A0221109 only. Safety analysis set included all subjects who were enrolled and received at least one dose of study medication in study A0221109. Here, 'Number of subjects analysed' = subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

A0221109: Baseline, Week 12

Notes:

[44] - 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: No statistical analysis was planned for this endpoint

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	2	0[45]	
Units: pegs				
arithmetic mean (standard deviation)				
Dominant hand: Baseline	25.0 (± 0.00)	25.0 (± 0.00)	()	
Dominant hand: Change at Week 12	0.0 (± 0.00)	0.0 (± 0.00)	()	
Non-dominant hand: Baseline	25.0 (± 0.00)	25.0 (± 0.00)	()	
Non-dominant hand: Change at Week 12	0.0 (± 0.00)	0.0 (± 0.00)	()	

Notes:

[45] - No subject was of age 9 years and above.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Grooved Pegboard Test (25 Pegs Group) at Week 28- Number of Pegs Placed Correctly: Study A0221109

End point title	Change From Baseline in Grooved Pegboard Test (25 Pegs Group) at Week 28- Number of Pegs Placed Correctly: Study A0221109[46]

End point description:

The grooved pegboard test was a manipulative dexterity test that assessed psychomotor speed, fine motor control, and rapid-visual motor coordination. 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. In this endpoint data for dominant and non-dominant hand have been reported separately. Data for this endpoint was planned to be analysed for each treatment group of Study A0221109 only. Safety analysis set included all subjects who were enrolled and received at least one dose of study medication in study A0221109. Here, 'Number of subjects analysed' = subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

A0221109: Baseline, Week 28

Notes:

[46] - 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: No statistical analysis was planned for this endpoint

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	2	0[47]	
Units: pegs				
arithmetic mean (standard deviation)				
Dominant hand	0.0 (± 0.00)	0.0 (± 0.00)	()	
Non-dominant hand	0.0 (± 0.00)	0.0 (± 0.00)	()	

Notes:

[47] - No subject was of age 9 years and above.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Grooved Pegboard Test (25 Pegs Group) at Final Visit- Number of Pegs Placed Correctly: Study A0221109

End point title	Change From Baseline in Grooved Pegboard Test (25 Pegs Group) at Final Visit- Number of Pegs Placed Correctly: Study A0221109[48]

End point description:

The grooved pegboard test was a manipulative dexterity test that assessed psychomotor speed, fine motor control, and rapid-visual motor coordination. 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. In this endpoint data for dominant and non-dominant hand have been reported separately. Data for this endpoint was planned to be analysed for each treatment group of Study A0221109 only. Safety analysis set included all subjects who were enrolled and received at least one dose of study medication in Study A0221109. Here, 'Number of subjects analysed' = subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

A0221109: Baseline, Final visit (Week 28 for subjects who completed the study or in case of early withdrawal the last assessment before Week 28 was considered to be the final visit)

Notes:

[48] - 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: No statistical analysis was planned for this endpoint

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	2	0[49]	
Units: pegs				
arithmetic mean (standard deviation)				
Dominant hand	0.0 (± 0.00)	0.0 (± 0.00)	()	
Non-dominant hand	0.0 (± 0.00)	0.0 (± 0.00)	()	

Notes:

[49] - No subjects were of age >=9 years.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Vital Sign (Blood Pressure) at Week 12: Study A0221109

End point title	Change From Baseline in Vital Sign (Blood Pressure) at Week 12: Study A0221109[50]

End point description:

Systolic blood and diastolic blood pressure were evaluated for examination of vital signs. Data for this endpoint was planned to be analysed for each treatment group of study A0221109 only. Safety analysis set included all subjects who were enrolled and received at least one dose of study medication in study A0221109.

End point type	Primary

End point timeframe:

A0221109: Baseline, Week 12

Notes:

[50] - 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: No statistical analysis was planned for this endpoint

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	7	3	
Units: millimeter of mercury				
arithmetic mean (standard deviation)				
Systolic blood pressure	6.0 (± 4.24)	2.1 (± 9.65)	5.0 (± 14.11)	
Diastolic blood pressure	10.5 (± 4.95)	-0.9 (± 8.90)	6.3 (± 15.31)	

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Vital Sign (Blood Pressure) at Week 28: Study A0221109

End point title	Change From Baseline in Vital Sign (Blood Pressure) at Week 28: Study A0221109[51]

End point description:

Systolic blood and diastolic blood pressure were evaluated for examination of vital signs. Data for this endpoint was planned to be analysed for each treatment group of study A0221109 only. Safety analysis set included all subjects who were enrolled and received at least one dose of study medication in study A0221109. Here, 'Number of subjects analysed' = subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

A0221109: Baseline, Week 28

Notes:

[51] - 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: No statistical analysis was planned for this endpoint

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	6	3	
Units: millimeter of mercury				
arithmetic mean (standard deviation)				
Systolic blood pressure	8.5 (± 16.26)	5.7 (± 11.18)	9.7 (± 2.52)	
Diastolic blood pressure	12.0 (± 4.24)	5.3 (± 9.03)	10.7 (± 2.52)	

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Vital Sign (Blood Pressure) at Final Visit: Study A0221109

End point title	Change From Baseline in Vital Sign (Blood Pressure) at Final Visit: Study A0221109[52]

End point description:

Systolic blood and diastolic blood pressure were evaluated for examination of vital sign. Data for this endpoint was planned to be analysed for each treatment group of study A0221109 only. Safety analysis

set included all subjects who were enrolled and received at least one dose of study medication in study A0221109.

End point type	Primary

End point timeframe:

A0221109: Baseline, Final visit (Week 28 for subjects who completed the study or in case of early withdrawal the last assessment before Week 28 was considered to be the final visit)

Notes:

[52] - 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: No statistical analysis was planned for this endpoint

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	7	3	
Units: millimeter of mercury				
arithmetic mean (standard deviation)				
Systolic blood pressure	8.5 (± 16.26)	5.1 (± 10.30)	9.7 (± 2.52)	
Diastolic blood pressure	12.0 (± 4.24)	4.6 (± 8.48)	10.7 (± 2.52)	

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Vital Sign (Pulse Rate) at Week 12: Study A0221109

End point title	Change From Baseline in Vital Sign (Pulse Rate) at Week 12: Study A0221109[53]

End point description:

Pulse rate was evaluated for examination of vital sign. Data for this endpoint was planned to be analysed for each treatment group of study A0221109 only. Safety analysis set included all subjects who were enrolled and received at least one dose of study medication in study A0221109.

End point type	Primary

End point timeframe:

A0221109: Baseline, Week 12

Notes:

[53] - 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: No statistical analysis was planned for this endpoint

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	7	3	
Units: beats per minute				
arithmetic mean (standard deviation)	0.0 (± 18.38)	2.4 (± 12.53)	-8.0 (± 2.00)	

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Vital Sign (Pulse Rate) at Week 28: Study A0221109

End point title	Change From Baseline in Vital Sign (Pulse Rate) at Week 28: Study A0221109[54]

End point description:

Pulse rate was evaluated for examination of vital sign. Data for this endpoint was planned to be analysed for each treatment group of study A0221109 only. Safety analysis set included all subjects who were enrolled and received at least one dose of study medication in study A0221109. Here, 'Number of subjects analysed' = subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

A0221109: Baseline, Week 28

Notes:

[54] - 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: No statistical analysis was planned for this endpoint

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	6	3	
Units: beats per minute				
arithmetic mean (standard deviation)	-3.5 (± 6.36)	-2.7 (± 8.82)	-3.7 (± 9.61)	

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Vital Sign (Pulse Rate) at Final Visit: Study A0221109

End point title	Change From Baseline in Vital Sign (Pulse Rate) at Final Visit: Study A0221109[55]

End point description:

Pulse rate was evaluated for examination of vital sign. Data for this endpoint was planned to be analysed for each treatment group of study A0221109 only. Safety analysis set included all subjects who were enrolled and received at least one dose of study medication in study A0221109.

End point type	Primary

End point timeframe:

A0221109: Baseline, Final visit (Week 28 for subjects who completed the study or in case of early withdrawal the last assessment before Week 28 was considered to be the final visit)

Notes:

[55] - 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: No statistical analysis was planned for this endpoint

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	7	3	
Units: beats per minute				
arithmetic mean (standard deviation)	-3.5 (± 6.36)	-1.4 (± 8.70)	-3.7 (± 9.61)	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Adverse Event Urinary Tract Infections (UTI): Merged Data of Studies A0221047 and A0221109

End point title	Number of Subjects With Adverse Event Urinary Tract Infections (UTI): Merged Data of Studies A0221047 and A0221109[56]

End point description:

UTI data were summarized for each cohort, each treatment group and the total of treatment groups, using the merged data of studies A0221047 and A0221109 as planned. Safety analysis set included all subjects who were enrolled and received at least one dose of study medication in Study A0221109.

End point type	Primary

End point timeframe:

Up to a maximum of 56 weeks (24 weeks of treatment in A0221047 and 32 weeks [28 weeks treatment + 4 weeks follow up post last dose] in A0221109)

Notes:

[56] - 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: No statistical analysis was planned for this endpoint

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	Cohort 1
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	2	7	3	2
Units: subjects	0	1	0	0

End point values	Cohort 2	Total of Treatment Groups		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	10	12		
Units: subjects	1	1		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Clinical Laboratory Abnormalities

End point title	Number of Subjects With Clinical Laboratory Abnormalities[57]

End point description:

Hematology: hemoglobin, 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*UL; basophils, eosinophils, monocytes >1.2*ULN. Clinical chemistry: bilirubin, direct bilirubin >1.5*ULN; aspartate aminotransferase (AT), alanine AT, gamma glutamyl transferase, lactate dehydrogenase, alkaline phosphatase >3.0*ULN; protein, albumin <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, bicarbonate <0.9*LLN>1.1*ULN; glucose <0.6*LLN>1.5*ULN; creatine kinase >2.0*ULN. Urinalysis: specific gravity <1.003>1.030, pH <4.5>8, glucose, ketones, protein, hemoglobin, nitrite, leukocyte esterase >=1; erythrocytes, leukocytes >=20; epithelial cells >=6, bacteria >20, hyaline casts >1. Data for this endpoint was planned to be analysed for each treatment group of study A0221109 only. Safety analysis set analyzed.

End point type	Primary

End point timeframe:

Baseline to 28 weeks of treatment in A0221109

Notes:

[57] - 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: No statistical analysis was planned for this endpoint

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	7	3	
Units: subjects	2	6	2	

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Post-Void Residual (PVR) Volume at Week 12: Study A0221109

End point title	Change From Baseline in Post-Void Residual (PVR) Volume at Week 12: Study A0221109[58]

End point description:

Post-void residual volume was assessed by an ultrasound. PVR volume was assessed only in subjects who did not perform clean intermittent catheterization or in any subjects who had >1 UTI during the study. Data for this endpoint was planned to be analysed for each treatment group of study A0221109 only. Safety analysis set included all subjects who were enrolled and received at least one dose of study medication in study A0221109. All subjects performed clean intermittent catheterization, hence were not eligible for post-void residual volume assessment.

End point type	Primary

End point timeframe:

A0221109: Baseline, Week 12

Notes:

[58] - 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: No statistical analysis was planned for this endpoint

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[59]	0[60]	0[61]	
Units: milliliter				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[59] - No subject was eligible for post-void residual volume assessment.

[60] - No subject was eligible for post-void residual volume assessment.

[61] - No subject was eligible for post-void residual volume assessment.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Post-Void Residual (PVR) Volume at Week 28: Study A0221109

End point title	Change From Baseline in Post-Void Residual (PVR) Volume at Week 28: Study A0221109[62]

End point description:

Post-void residual volume measurement was measured by an ultrasound. PVR volume was only assessed for subjects who did not perform clean intermittent catheterization or in any subjects who had >1 UTI during the study. Data for this endpoint was planned to be analysed for each treatment group of study A0221109 only. Safety analysis set included all subjects who were enrolled and received at least one dose of study medication in study A0221109. All subjects performed clean intermittent catheterization, hence were not eligible for post-void residual volume assessment.

End point type	Primary

End point timeframe:

A0221109: Baseline, Week 28

Notes:

[62] - 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: No statistical analysis was planned for this endpoint

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[63]	0[64]	0[65]	
Units: milliliter				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[63] - No subject was eligible for post-void residual volume assessment.

[64] - No subject was eligible for post-void residual volume assessment.

[65] - No subject was eligible for post-void residual volume assessment.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Post-Void Residual (PVR) Volume at Final Visit: Study A0221109

End point title	Change From Baseline in Post-Void Residual (PVR) Volume at Final Visit: Study A0221109[66]

End point description:

Post-void residual volume measurement was measured by an ultrasound. PVR volume was only assessed for subjects who did not perform clean intermittent catheterization or in any subjects who had

>1 UTI during the study. Data for this endpoint was planned to be analysed for each treatment group of study A0221109 only. Safety analysis set included all subjects who were enrolled and received at least one dose of study medication in study A0221109. All subjects performed clean intermittent catheterization, hence were not eligible for post-void residual volume assessment.

End point type	Primary

End point timeframe:

A0221109: Baseline, Final visit (Week 28 for subjects who completed the study or in case of early withdrawal the last assessment before Week 28 was considered to be the final visit)

Notes:

[66] - 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: No statistical analysis was planned for this endpoint

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[67]	0[68]	0[69]	
Units: milliliter				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[67] - No subject was eligible for post-void residual volume assessment.

[68] - No subject was eligible for post-void residual volume assessment.

[69] - No subject was eligible for post-void residual volume assessment.

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Maximum Cystometric Bladder Capacity at Week 12 of study A0221047 and at Week 28 and Final Visit of Study A0221109

End point title	Change From Baseline in Maximum Cystometric Bladder Capacity at Week 12 of study A0221047 and at Week 28 and Final Visit of Study A0221109

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). Maximum cystometric bladder capacity was summarized for each cohort, each treatment group and total of treatment groups, using the merged data of studies A0221047 and A0221109 as planned. Full analysis set (FAS) included all subjects who were enrolled and received at least one dose of study medication and had at least 1 observation in efficacy endpoint data after baseline visit in study A0221109. Here, 'n' = subjects evaluable for this endpoint for specified rows.

End point type	Secondary

End point timeframe:

Study A0221047: Baseline, Week 12; Study A0221109: Week 28, Final Visit (Week 28 for subjects who completed the study or in case of early withdrawal the last assessment before Week 28 was considered to be the final visit)

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	Cohort 1
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	2	7	3	2
Units: milliliter				
arithmetic mean (standard deviation)				
Baseline (n =2, 7, 3, 2, 10, 12)	181.0 (± 28.28)	149.7 (± 38.49)	102.3 (± 48.95)	181.0 (± 28.28)

Change at Week 12 (n =2, 7, 3, 2, 10, 12)	153.0 (± 56.57)	37.6 (± 28.83)	55.3 (± 38.76)	153.0 (± 56.57)
Change at Week 28 (n =2, 6, 3, 2, 9, 11)	121.5 (± 30.41)	32.8 (± 52.42)	48.0 (± 67.55)	121.5 (± 30.41)
Change at Final Visit (n =2, 6, 3, 2, 9, 11)	121.5 (± 30.41)	32.8 (± 52.42)	48.0 (± 67.55)	121.5 (± 30.41)

End point values	Cohort 2	Total of Treatment Groups		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	10	12		
Units: milliliter				
arithmetic mean (standard deviation)				
Baseline (n =2, 7, 3, 2, 10, 12)	135.5 (± 45.21)	143.1 (± 45.37)		
Change at Week 12 (n =2, 7, 3, 2, 10, 12)	42.9 (± 31.01)	61.3 (± 53.98)		
Change at Week 28 (n =2, 6, 3, 2, 9, 11)	37.9 (± 53.99)	53.1 (± 59.74)		
Change at Final Visit (n =2, 6, 3, 2, 9, 11)	37.9 (± 53.99)	53.1 (± 59.74)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Detrusor Pressure at Maximum Bladder Capacity at Week 12 of study A0221047 and at Week 28 and Final Visit of Study A0221109

End point title	Change From Baseline in Detrusor Pressure at Maximum Bladder Capacity at Week 12 of study A0221047 and at Week 28 and Final Visit of Study A0221109

End point description:

Detrusor pressure (cm H2O) at maximum urinary bladder capacity was measured using urodynamic testing. Detrusor pressure was summarized for each cohort, each treatment group and total of treatment groups, using the merged data of studies A0221047 and A0221109 as planned. FAS included all subjects who were enrolled and received at least one dose of study medication and had at least 1 observation in efficacy endpoint data after baseline visit in study A0221109. Here, 'n' = subjects evaluable for this endpoint for specified rows.

End point type	Secondary

End point timeframe:

Study A0221047: Baseline, Week 12; Study A0221109: Week 28, Final Visit (Week 28 for subjects who completed the study or in case of early withdrawal the last assessment before Week 28 was considered to be the final visit)

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	Cohort 1
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	2	7	3	2
Units: cm H2O				
arithmetic mean (standard deviation)				
Baseline (n =2, 7, 3, 2, 10, 12)	29.0 (± 8.49)	32.4 (± 11.57)	58.3 (± 57.55)	29.0 (± 8.49)
Change at Week 12 (n =2, 7, 3, 2, 10, 12)	-5.5 (± 0.71)	-6.0 (± 7.85)	-31.7 (± 43.73)	-5.5 (± 0.71)
Change at Week 28 (n =2, 6, 3, 2, 9, 11)	-7.0 (± 0.00)	-2.8 (± 2.86)	-7.3 (± 47.44)	-7.0 (± 0.00)
Change at Final Visit (n =2, 6, 3, 2, 9, 11)	-7.0 (± 0.00)	-2.8 (± 2.86)	-7.3 (± 47.44)	-7.0 (± 0.00)

End point values	Cohort 2	Total of Treatment Groups		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	10	12		
Units: cm H2O				
arithmetic mean (standard deviation)				
Baseline (n =2, 7, 3, 2, 10, 12)	40.2 (± 31.34)	38.3 (± 28.79)		
Change at Week 12 (n =2, 7, 3, 2, 10, 12)	-13.7 (± 24.90)	-12.3 (± 22.74)		
Change at Week 28 (n =2, 6, 3, 2, 9, 11)	-4.3 (± 23.93)	-4.8 (± 21.43)		
Change at Final Visit (n =2, 6, 3, 2, 9, 11)	-4.3 (± 23.93)	-4.8 (± 21.43)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Presence of Involuntary Detrusor Contraction (IDC) at Baseline and Week 12 of study A0221047 and at Week 28 and Final Visit of Study A0221109

End point title	Number of Subjects With Presence of Involuntary Detrusor Contraction (IDC) at Baseline and Week 12 of study A0221047 and at Week 28 and Final Visit of Study A0221109

End point description:

Subjects with presence of IDC was summarized for each cohort, each treatment group and total of treatment groups, using the merged data of studies A0221047 and A0221109 as planned. FAS included all subjects who were enrolled and received at least one dose of study medication and had at least 1 observation in efficacy endpoint data after baseline visit in study A0221109.

End point type	Secondary

End point timeframe:

Study A0221047: Baseline, Week 12; Study A0221109: Week 28, Final Visit (Week 28 for subjects who completed the study or in case of early withdrawal the last assessment before Week 28 was considered to be the final visit)

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	Cohort 1
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	2	7	3	2
Units: subjects				
Baseline	1	7	3	1
Week 12	0	4	3	0
Week 28	0	5	3	0
Final Visit	0	5	3	0

End point values	Cohort 2	Total of Treatment Groups		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	10	12		
Units: subjects				
Baseline	10	11		
Week 12	7	7		
Week 28	8	8		
Final Visit	8	8		

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 of study A0221047 and at Week 28 and Final Visit of Study A0221109

End point title	Change From Baseline in Bladder Volume at First Involuntary Detrusor Contraction (IDC) at Week 12 of study A0221047 and at Week 28 and Final Visit of Study A0221109

End point description:

Bladder volume at first IDC was measured using urodynamic testing. Bladder volume at first IDC was summarized for each cohort, each treatment group and total of treatment groups, using the merged data of studies A0221047 and A0221109 as planned. 9999 =standard deviation was not estimable since only 1 subjects was analysed. 99999 =Arithmetic mean and SD were not estimable since no subjects were analysed. FAS included all subjects who were enrolled and received at least one dose of study medication and had at least 1 observation in efficacy endpoint data after baseline visit in study A0221109. Here, 'Number of subjects analysed' = subjects evaluable for this endpoint. Here, 'n' = subjects evaluable for this endpoint for specified rows.

End point type	Secondary

End point timeframe:

Study A0221047: Baseline, Week 12; Study A0221109: Week 28, Final Visit (Week 28 for subjects who completed the study or in case of early withdrawal the last assessment before Week 28 was considered to be the final visit)

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	Cohort 1
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	1	7	3	1
Units: milliliter				
arithmetic mean (standard deviation)				
Baseline (n =1, 7, 3, 1, 10, 11)	175.0 (± 9999)	48.1 (± 36.57)	50.3 (± 22.14)	175.0 (± 9999)
Change at Week 12 (n =0, 4, 3, 0, 7, 7)	99999 (± 99999)	113.8 (± 68.55)	70.0 (± 4.58)	99999 (± 99999)
Change at Week 28 (n =0, 5, 3, 0, 8, 8)	99999 (± 99999)	38.6 (± 24.46)	70.0 (± 50.11)	99999 (± 99999)
Change at Final Visit (n =0, 5, 3, 8, 0, 8,)	99999 (± 99999)	38.6 (± 24.46)	70.0 (± 50.11)	99999 (± 99999)

End point values	Cohort 2	Total of Treatment Groups		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	10	11		
Units: milliliter				
arithmetic mean (standard deviation)				
Baseline (n =1, 7, 3, 1, 10, 11)	48.8 (± 31.65)	60.3 (± 48.47)		
Change at Week 12 (n =0, 4, 3, 0, 7, 7)	95.0 (± 53.88)	95.0 (± 53.88)		
Change at Week 28 (n =0, 5, 3, 0, 8, 8)	50.4 (± 36.38)	50.4 (± 36.38)		
Change at Final Visit (n =0, 5, 3, 8, 0, 8,)	50.4 (± 36.38)	50.4 (± 36.38)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Bladder Compliance at Week 12 of study A0221047 and at Week 28 and Final Visit of Study A0221109

End point title	Change From Baseline in Bladder Compliance at Week 12 of study A0221047 and at Week 28 and Final Visit of Study A0221109

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). Bladder Compliance was summarized for each cohort, each treatment group and total of treatment groups, using the merged data of studies A0221047 and A0221109 as planned. FAS included all subjects who were enrolled and received at least one dose of study medication and had at least 1 observation in efficacy endpoint data after baseline visit in study A0221109. Here, 'n' = subjects evaluable for this endpoint for specified rows.

End point type	Secondary

End point timeframe:

Study A0221047: Baseline, Week 12; Study A0221109: Week 28, Final Visit (Week 28 for subjects who completed the study or in case of early withdrawal the last assessment before Week 28 was considered

to be the final visit)

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	Cohort 1
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	2	7	3	2
Units: milliliter per cm H2O				
arithmetic mean (standard deviation)				
Baseline (n =2, 7, 3, 2, 10, 12)	7.00 (± 2.828)	8.16 (± 5.668)	4.20 (± 2.307)	7.00 (± 2.828)
Change at Week 12 (n =2, 7, 3, 2, 10, 12)	9.00 (± 7.071)	23.34 (± 55.493)	12.40 (± 14.855)	9.00 (± 7.071)
Change at Week 28 (n =2, 6, 3, 2, 9, 11)	8.65 (± 6.152)	13.18 (± 18.628)	13.30 (± 15.836)	8.65 (± 6.152)
Change at Final Visit (n =2, 6, 3, 2, 9, 11)	8.65 (± 6.152)	13.18 (± 18.628)	13.30 (± 15.836)	8.65 (± 6.152)

End point values	Cohort 2	Total of Treatment Groups		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	10	12		
Units: milliliter per cm H2O				
arithmetic mean (standard deviation)				
Baseline (n =2, 7, 3, 2, 10, 12)	6.97 (± 5.124)	6.98 (± 4.712)		
Change at Week 12 (n =2, 7, 3, 2, 10, 12)	20.06 (± 46.151)	18.22 (± 42.021)		
Change at Week 28 (n =2, 6, 3, 2, 9, 11)	13.22 (± 16.721)	12.39 (± 15.194)		
Change at Final Visit (n =2, 6, 3, 2, 9, 11)	13.22 (± 16.721)	12.39 (± 15.194)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Mean Number of Micturitions per 24 Hours at Week 12 of study A0221047 and at Week 28 and Final Visit of Study A0221109

End point title	Change From Baseline in Mean Number of Micturitions per 24 Hours at Week 12 of study A0221047 and at Week 28 and Final Visit of Study A0221109

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. Data was summarized for each cohort, each treatment group and total of treatment groups, using the merged data of studies A0221047 and A0221109 as planned. FAS included all subjects who were enrolled and received at least one dose of study medication and had at least 1 observation in efficacy endpoint data after baseline visit in study A0221109. Here, 'Number of subjects analysed' = subjects evaluable for this endpoint. No subject in reporting arms "Cohort 1", "Fesoterodine

8 mg Tablet” and “Fesoterodine 4 mg Capsule” had >0 micturitions at baseline.

End point type	Secondary

End point timeframe:

Study A0221047: Baseline, Week 12; Study A0221109: Week 28, Final Visit (Week 28 for subjects who completed the study or in case of early withdrawal the last assessment before Week 28 was considered to be the final visit)

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	Cohort 1
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	0[70]	4	0[71]	0[72]
Units: micturitions per 24 hours				
arithmetic mean (standard deviation)				
Baseline	()	4.58 (± 4.541)	()	()
Change at Week 12	()	-1.50 (± 1.036)	()	()
Change at Week 28	()	-1.08 (± 0.631)	()	()
Change at Final Visit	()	-1.08 (± 0.631)	()	()

Notes:

[70] - No subjects had >0 micturitions at baseline.

[71] - No subjects had >0 micturitions at baseline.

[72] - No subjects had >0 micturitions at baseline.

End point values	Cohort 2	Total of Treatment Groups		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	4	4		
Units: micturitions per 24 hours				
arithmetic mean (standard deviation)				
Baseline	4.58 (± 4.541)	4.58 (± 4.541)		
Change at Week 12	-1.50 (± 1.036)	-1.50 (± 1.036)		
Change at Week 28	-1.08 (± 0.631)	-1.08 (± 0.631)		
Change at Final Visit	-1.08 (± 0.631)	-1.08 (± 0.631)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Mean Number of Catheterizations per 24 Hours at Week 12 of study A0221047 and at Week 28 and Final Visit of Study A0221109

End point title	Change From Baseline in Mean Number of Catheterizations per 24 Hours at Week 12 of study A0221047 and at Week 28 and Final Visit of Study A0221109

End point description:

The mean number of catheterizations per 24 hours were calculated as the total number of

catheterizations 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 catheterizations at Baseline. Data was summarized for each cohort, each treatment group and total of treatment groups, using the merged data of studies A0221047 and A0221109 as planned. FAS included all subjects who were enrolled and received at least one dose of study medication and had at least 1 observation in efficacy endpoint data after baseline visit in study A0221109. Here, 'n' = subjects evaluable for this endpoint for specified rows.

End point type	Secondary

End point timeframe:

Study A0221047: Baseline, Week 12; Study A0221109: Week 28, Final Visit (Week 28 for subjects who completed the study or in case of early withdrawal the last assessment before Week 28 was considered to be the final visit)

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	Cohort 1
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	2	7	3	2
Units: catheterizations per 24 hours				
arithmetic mean (standard deviation)				
Baseline (n =2, 7, 3, 2, 10, 12)	5.33 (± 0.943)	4.24 (± 1.641)	5.00 (± 0.000)	5.33 (± 0.943)
Change at Week 12 (n =2, 7, 3, 2, 10, 12)	0.00 (± 0.471)	0.03 (± 0.420)	0.11 (± 0.192)	0.00 (± 0.471)
Change at Week 28 (n =2, 6, 3, 2, 9, 11)	0.33 (± 0.000)	-0.19 (± 0.267)	0.11 (± 0.192)	0.33 (± 0.000)
Change at Final Visit (n =2, 7, 3, 2, 10, 12)	0.33 (± 0.000)	-0.21 (± 0.249)	0.11 (± 0.192)	0.33 (± 0.000)

End point values	Cohort 2	Total of Treatment Groups		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	10	12		
Units: catheterizations per 24 hours				
arithmetic mean (standard deviation)				
Baseline (n =2, 7, 3, 2, 10, 12)	4.47 (± 1.390)	4.61 (± 1.332)		
Change at Week 12 (n =2, 7, 3, 2, 10, 12)	0.05 (± 0.357)	0.04 (± 0.353)		
Change at Week 28 (n =2, 6, 3, 2, 9, 11)	-0.09 (± 0.278)	-0.02 (± 0.302)		
Change at Final Visit (n =2, 7, 3, 2, 10, 12)	-0.12 (± 0.273)	-0.04 (± 0.303)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Mean Number of Micturitions or Catheterizations Combined per 24 Hours at Week 12 of study A0221047 and at

Week 28 and Final Visit of Study A0221109

End point title	Change From Baseline in Mean Number of Micturitions or Catheterizations Combined per 24 Hours at Week 12 of study A0221047 and at Week 28 and Final Visit of Study A0221109

End point description:

The mean number of micturitions and catheterizations combined per 24 hours were calculated as the total number of micturitions and catheterizations 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 (hr) period. This endpoint was only calculated for subjects with >0 micturitions or catheterizations at Baseline. Data was summarized for each cohort, each treatment group and total of treatment groups, using the merged data of studies A0221047 and A0221109 as planned. FAS included all subjects who were enrolled and received at least one dose of study medication and had at least 1 observation in efficacy endpoint data after baseline visit in study A0221109. Here, 'n' = subjects evaluable for this endpoint for specified rows.

End point type	Secondary

End point timeframe:

Study A0221047: Baseline, Week 12; Study A0221109: Week 28, Final Visit (Week 28 for subjects who completed the study or in case of early withdrawal the last assessment before Week 28 was considered to be the final visit)

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	Cohort 1
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	2	7	3	2
Units: micturitions or catheterizations/24 hr				
arithmetic mean (standard deviation)				
Baseline (n =2, 7, 3, 2, 10, 12)	5.33 (± 0.943)	6.86 (± 3.259)	5.00 (± 0.000)	5.33 (± 0.943)
Change at Week 12 (n =2, 7, 3, 2, 10, 12)	0.00 (± 0.471)	-0.83 (± 1.264)	0.11 (± 0.192)	0.00 (± 0.471)
Change at Week 28 (n =2, 6, 3, 2, 9, 11)	0.33 (± 0.000)	-0.92 (± 0.665)	0.11 (± 0.192)	0.33 (± 0.000)
Change at Final Visit (n =2, 7, 3, 2, 10, 12)	0.33 (± 0.000)	-0.83 (± 0.645)	0.11 (± 0.192)	0.33 (± 0.000)

End point values	Cohort 2	Total of Treatment Groups		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	10	12		
Units: micturitions or catheterizations/24 hr				
arithmetic mean (standard deviation)				
Baseline (n =2, 7, 3, 2, 10, 12)	6.30 (± 2.808)	6.14 (± 2.584)		
Change at Week 12 (n =2, 7, 3, 2, 10, 12)	-0.55 (± 1.131)	-0.46 (± 1.055)		
Change at Week 28 (n =2, 6, 3, 2, 9, 11)	-0.57 (± 0.741)	-0.41 (± 0.758)		
Change at Final Visit (n =2, 7, 3, 2, 10, 12)	-0.55 (± 0.703)	-0.40 (± 0.723)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Mean Number of Incontinence Episodes per 24 Hours at Week 12 of study A0221047 and at Week 28 and Final Visit of Study A0221109

End point title	Change From Baseline in Mean Number of Incontinence Episodes per 24 Hours at Week 12 of study A0221047 and at Week 28 and Final Visit of Study A0221109

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. Data was summarized for each cohort, each treatment group and total of treatment groups, using the merged data of studies A0221047 and A0221109 as planned. FAS included all subjects who were enrolled and received at least one dose of study medication and had at least 1 observation in efficacy endpoint data after baseline visit in study A0221109. Here, 'n' = subjects evaluable for this endpoint for specified rows.

End point type	Secondary

End point timeframe:

Study A0221047: Baseline, Week 12; Study A0221109: Week 28, Final Visit (Week 28 for subjects who completed the study or in case of early withdrawal the last assessment before Week 28 was considered to be the final visit)

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	Cohort 1
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	2	7	3	2
Units: incontinence episodes per 24 hours				
arithmetic mean (standard deviation)				
Baseline (n =2, 7, 3, 2, 10, 12)	1.17 (± 0.236)	3.48 (± 2.768)	3.89 (± 0.770)	1.17 (± 0.236)
Change at Week 12 (n =2, 7, 3, 2, 10, 12)	0.50 (± 0.236)	-0.26 (± 2.074)	0.00 (± 0.667)	0.50 (± 0.236)
Change at Week 28 (n =2, 6, 3, 2, 9, 11)	1.83 (± 0.707)	-0.42 (± 1.577)	-0.11 (± 1.644)	1.83 (± 0.707)
Change at Final Visit (n =2, 7, 3, 2, 10, 12)	1.83 (± 0.707)	0.17 (± 2.110)	-0.11 (± 1.644)	1.83 (± 0.707)

End point values	Cohort 2	Total of Treatment Groups		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	10	12		

Units: incontinence episodes per 24 hours				
arithmetic mean (standard deviation)				
Baseline (n =2, 7, 3, 2, 10, 12)	3.60 (± 2.298)	3.19 (± 2.285)		
Change at Week 12 (n =2, 7, 3, 2, 10, 12)	-0.18 (± 1.726)	-0.07 (± 1.586)		
Change at Week 28 (n =2, 6, 3, 2, 9, 11)	-0.31 (± 1.501)	0.08 (± 1.615)		
Change at Final Visit (n =2, 7, 3, 2, 10, 12)	0.08 (± 1.894)	0.38 (± 1.856)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Mean Number of Urgency Episodes per 24 Hours at Week 12 of study A0221047 and at Week 28 and Final Visit of Study A0221109

End point title	Change From Baseline in Mean Number of Urgency Episodes per 24 Hours at Week 12 of study A0221047 and at Week 28 and Final Visit of Study A0221109

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 sensate subjects with >0 urgency episodes at Baseline. Data was summarized for each cohort, each treatment group and total of treatment groups, using the merged data of studies A0221047 and A0221109 as planned. 9999 =standard deviation was not estimable since only one subjects was analysed. FAS was analyzed. Here, 'Number of subjects analysed' = subjects evaluable for this endpoint. No sensate subjects for reporting arms "Cohort 1" and "Fesoterodine 8 mg Tablet" had >0 urgency episodes at baseline.

End point type	Secondary

End point timeframe:

Study A0221047: Baseline, Week 12; Study A0221109: Week 28, Final Visit (Week 28 for subjects who completed the study or in case of early withdrawal the last assessment before Week 28 was considered to be the final visit)

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	Cohort 1
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	0[73]	2	1	0[74]
Units: urgency episodes per 24 hours				
arithmetic mean (standard deviation)				
Baseline	()	0.75 (± 0.354)	0.33 (± 9999)	()
Change at Week 12	()	-0.75 (± 0.354)	-0.33 (± 9999)	()
Change at Week 28	()	-0.75 (± 0.354)	-0.33 (± 9999)	()
Change at Final Visit	()	-0.75 (± 0.354)	-0.33 (± 9999)	()

Notes:

[73] - No subject had >0 urgency episodes.

[74] - No subject had >0 urgency episodes.

End point values	Cohort 2	Total of Treatment Groups		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	3	3		
Units: urgency episodes per 24 hours				
arithmetic mean (standard deviation)				
Baseline	0.61 (± 0.347)	0.61 (± 0.347)		
Change at Week 12	-0.61 (± 0.347)	-0.61 (± 0.347)		
Change at Week 28	-0.61 (± 0.347)	-0.61 (± 0.347)		
Change at Final Visit	-0.61 (± 0.347)	-0.61 (± 0.347)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Mean Volume Voided per Micturition at Week 12 of study A0221047 and at Week 28 and Final Visit of Study A0221109

End point title	Change From Baseline in Mean Volume Voided per Micturition at Week 12 of study A0221047 and at Week 28 and Final Visit of Study A0221109

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 > 0. This endpoint included only subjects who actually had the records of volume voided per micturition. Data was summarized for each cohort, each treatment group and total of treatment groups, using the merged data of studies A0221047 and A0221109 as planned. Only subjects who actually had the records of volume voided per micturition were reported. FAS included all subjects who were enrolled and received at least one dose of study medication and had at least 1 observation in efficacy endpoint data after baseline visit in Study A0221109. Here, 'Number of subjects analysed' = subjects evaluable for this endpoint. No subject in reporting arms "Cohort 1", "Fesoterodine 8 mg Tablet" and "Fesoterodine 4 mg Capsule" had the records of volume voided per micturition.

End point type	Secondary

End point timeframe:

Study A0221047: Baseline, Week 12; Study A0221109: Week 28, Final Visit (Week 28 for subjects who completed the study or in case of early withdrawal the last assessment before Week 28 was considered to be the final visit)

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	Cohort 1
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	0[75]	2	0[76]	0[77]
Units: milliliter per micturition				
arithmetic mean (standard deviation)				

Baseline	()	73.42 (± 42.309)	()	()
Change at Week 12	()	15.77 (± 6.924)	()	()
Change at Week 28	()	4.75 (± 14.496)	()	()
Change at Final Visit	()	4.75 (± 14.496)	()	()

Notes:

[75] - No subjects had records of volume voided per micturition.

[76] - No subjects had records of volume voided per micturition.

[77] - No subjects had records of volume voided per micturition.

End point values	Cohort 2	Total of Treatment Groups		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2	2		
Units: milliliter per micturition				
arithmetic mean (standard deviation)				
Baseline	73.42 (± 42.309)	73.42 (± 42.309)		
Change at Week 12	15.77 (± 6.924)	15.77 (± 6.924)		
Change at Week 28	4.75 (± 14.496)	4.75 (± 14.496)		
Change at Final Visit	4.75 (± 14.496)	4.75 (± 14.496)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Mean Volume Voided per Catheterization at Week 12 of study A0221047 and at Week 28 and Final Visit of Study A0221109

End point title	Change From Baseline in Mean Volume Voided per Catheterization at Week 12 of study A0221047 and at Week 28 and Final Visit of Study A0221109

End point description:

The mean volume per catheterization was calculated as sum of voided volume divided by the total number of catheterization, with a recorded voided volume >0. This endpoint included only subjects who actually had the records of volume voided per catherization. Data was summarized for each cohort, each treatment group and total of treatment groups, using the merged data of studies A0221047 and A0221109 as planned. FAS included all subjects who were enrolled and received at least one dose of study medication and had at least 1 observation in efficacy endpoint data after baseline visit in Study A0221109. Here, 'n' = subjects evaluable for this endpoint for specified rows.

End point type	Secondary

End point timeframe:

Study A0221047: Baseline, Week 12; Study A0221109: Week 28, Final Visit (Week 28 for subjects who completed the study or in case of early withdrawal the last assessment before Week 28 was considered to be the final visit)

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	Cohort 1
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	2	7	3	2
Units: milliliter per catheterization				
arithmetic mean (standard deviation)				
Baseline (n =2, 7, 3, 2, 10, 12)	198.75 (± 44.194)	48.76 (± 39.230)	80.58 (± 39.841)	198.75 (± 44.194)
Change at Week 12 (n =2, 7, 3, 2, 10, 12)	-0.92 (± 21.095)	17.90 (± 17.038)	27.08 (± 32.086)	-0.92 (± 21.095)
Change at Week 28 (n =2, 6, 3, 2, 9, 11)	-29.42 (± 12.139)	8.72 (± 33.245)	17.28 (± 9.659)	-29.42 (± 12.139)
Change at Final Visit (n =2, 6, 3, 2, 9, 11)	-29.42 (± 12.139)	8.72 (± 33.245)	17.28 (± 9.659)	-29.42 (± 12.139)

End point values	Cohort 2	Total of Treatment Groups		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	10	12		
Units: milliliter per catheterization				
arithmetic mean (standard deviation)				
Baseline (n =2, 7, 3, 2, 10, 12)	58.31 (± 40.187)	81.72 (± 66.988)		
Change at Week 12 (n =2, 7, 3, 2, 10, 12)	20.66 (± 21.024)	17.06 (± 21.739)		
Change at Week 28 (n =2, 6, 3, 2, 9, 11)	11.58 (± 27.064)	4.12 (± 29.591)		
Change at Final Visit (n =2, 6, 3, 2, 9, 11)	11.58 (± 27.064)	4.12 (± 29.591)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Mean Volume Voided per Micturition or Catheterization at Week 12 of study A0221047 and at Week 28 and Final Visit of Study A0221109

End point title	Change From Baseline in Mean Volume Voided per Micturition or Catheterization at Week 12 of study A0221047 and at Week 28 and Final Visit of Study A0221109

End point description:

The mean voided volume per micturition or catheterization was calculated as sum of voided volume divided by the total number of micturition or catheterization episodes with a recorded voided volume >0. Data was summarized for each cohort, each treatment group and total of treatment groups, using the merged data of studies A0221047 and A0221109 as planned. FAS included all subjects who were enrolled and received at least one dose of study medication and had at least 1 observation in efficacy endpoint data after baseline visit in Study A0221109. Here, 'n' = subjects evaluable for this endpoint for specified rows.

End point type	Secondary

End point timeframe:

or Study A0221047: Baseline, Week 12; Study A0221109: Week 28, Final Visit (Week 28 for subjects who completed the study or in case of early withdrawal the last assessment before Week 28 was

considered to be the final visit)

End point values	Fesoterodine 8 mg Tablet	Fesoterodine 2 mg Capsule	Fesoterodine 4 mg Capsule	Cohort 1
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	2	7	3	2
Units: mL per micturition or catheterization				
arithmetic mean (standard deviation)				
Baseline (n =2, 7, 3, 2, 10, 12)	198.75 (± 44.194)	59.29 (± 33.550)	80.58 (± 39.841)	198.75 (± 44.194)
Change at Week 12 (n =2, 7, 3, 2, 10, 12)	-0.92 (± 21.095)	13.94 (± 7.801)	27.08 (± 32.086)	-0.92 (± 21.095)
Change at Week 28 (n =2, 6, 3, 2, 9, 11)	-29.42 (± 12.139)	9.86 (± 33.029)	17.28 (± 9.659)	-29.42 (± 12.139)
Change at Final Visit (n =2, 6, 3, 2, 9, 11)	-29.42 (± 12.139)	9.86 (± 33.029)	17.28 (± 9.659)	-29.42 (± 12.139)

End point values	Cohort 2	Total of Treatment Groups		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	10	12		
Units: mL per micturition or catheterization				
arithmetic mean (standard deviation)				
Baseline (n =2, 7, 3, 2, 10, 12)	65.68 (± 34.769)	87.86 (± 62.045)		
Change at Week 12 (n =2, 7, 3, 2, 10, 12)	17.88 (± 17.597)	14.75 (± 18.638)		
Change at Week 28 (n =2, 6, 3, 2, 9, 11)	12.34 (± 26.812)	4.75 (± 29.583)		
Change at Final Visit (n =2, 6, 3, 2, 9, 11)	12.34 (± 26.812)	4.75 (± 29.583)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to a maximum of 56 weeks (24 weeks of treatment in A0221047 and 32 weeks [28 weeks treatment + 4 weeks follow up post last dose] in A0221109)

Adverse event reporting additional description:

Safety analysis population was evaluated. AEs were summarized for each cohort (Cohort 1 and Cohort 2), each treatment group and the total of treatment groups , using the merged data of studies A0221047 and A0221109 as planned.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22.1

Reporting groups

Reporting group title	Cohort 2

Reporting group description:

Subjects of cohort 2 with body weight <=25 kg, who received either fesoterodine 2 mg or 4 mg capsule orally once daily in efficacy and safety phase in precedent study A0221047 and then continued same dose and dosage form of fesoterodine for 28 weeks in this LTE study.

Reporting group title	Cohort 1

Reporting group description:

Subjects of cohort 1 with body weight >25 kg, who received fesoterodine 4 mg or 8 mg PR tablet orally once daily for 24 weeks (12 weeks in each active comparator and safety extension phase) in precedent study A0221047 and then continued same dose and dosage form of fesoterodine for 28 weeks in this LTE study.

Reporting group title	Fesoterodine 2 mg Capsule

Reporting group description:

Subjects of cohort 2, with body weight <=25 kg, received fesoterodine 2 mg BIC capsules orally once daily for 24 weeks (12 weeks in each efficacy and safety extension phase) in precedent study and who continued to receive fesoterodine 2 mg BIC capsules orally once daily for another 28 weeks in this LTE study.

Reporting group title	Fesoterodine 8 mg Tablet

Reporting group description:

Subjects of cohort 1, with body weight > 25 kg, who received fesoterodine 8 mg PR tablet once daily for 24 weeks (12 weeks in each active comparator and safety extension phase) in precedent study A0221047 and who continued to receive fesoterodine 8 mg PR tablet orally once daily for another 28 weeks in this LTE study.

Reporting group title	Total of Treatment Groups

Reporting group description:

Total Subjects who received fesoterodine 8 mg PR tablet, fesoterodine 2 mg and 4 mg BIC capsules in precedent study A0221047 and continued to receive same treatment respectively in this LTE study.

Reporting group title	Fesoterodine 4 mg Capsule

Reporting group description:

Subjects of cohort 2, with body weight <=25 kg, received fesoterodine 2 mg BIC capsules orally once daily for 1 week and if well tolerated then fesoterodine 4 mg BIC capsules orally once daily for 11 weeks (in efficacy phase) and 12 weeks (in safety extension phase) in precedent study A0221047 and who continued to receive fesoterodine 4 mg BIC capsules orally once daily for another 28 weeks in this LTE study.

Serious adverse events	Cohort 2	Cohort 1	Fesoterodine 2 mg Capsule
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 10 (10.00%)	0 / 2 (0.00%)	1 / 7 (14.29%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Infections and infestations			
Urinary tract infection			
subjects affected / exposed	1 / 10 (10.00%)	0 / 2 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Fesoterodine 8 mg Tablet	Total of Treatment Groups	Fesoterodine 4 mg Capsule
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 2 (0.00%)	1 / 12 (8.33%)	0 / 3 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Infections and infestations			
Urinary tract infection			
subjects affected / exposed	0 / 2 (0.00%)	1 / 12 (8.33%)	0 / 3 (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

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

Non-serious adverse events	Cohort 2	Cohort 1	Fesoterodine 2 mg Capsule
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 10 (90.00%)	2 / 2 (100.00%)	6 / 7 (85.71%)
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 10 (0.00%)	1 / 2 (50.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	2 / 10 (20.00%)	1 / 2 (50.00%)	1 / 7 (14.29%)
occurrences (all)	3	1	2
Immune system disorders			

Seasonal allergy			
subjects affected / exposed	1 / 10 (10.00%)	0 / 2 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	1 / 10 (10.00%)	0 / 2 (0.00%)	1 / 7 (14.29%)
occurrences (all)	2	0	2
Upper respiratory tract inflammation			
subjects affected / exposed	2 / 10 (20.00%)	0 / 2 (0.00%)	1 / 7 (14.29%)
occurrences (all)	2	0	1
Product issues			
Device malfunction			
subjects affected / exposed	1 / 10 (10.00%)	0 / 2 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Investigations			
Urodynamics measurement abnormal			
subjects affected / exposed	1 / 10 (10.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Chillblains			
subjects affected / exposed	0 / 10 (0.00%)	1 / 2 (50.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 10 (0.00%)	1 / 2 (50.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Astigmatism			
subjects affected / exposed	1 / 10 (10.00%)	0 / 2 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Conjunctivitis allergic			
subjects affected / exposed	1 / 10 (10.00%)	0 / 2 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Myopia			
subjects affected / exposed	2 / 10 (20.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Strabismus			

subjects affected / exposed	1 / 10 (10.00%)	0 / 2 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Visual acuity reduced			
subjects affected / exposed	0 / 10 (0.00%)	1 / 2 (50.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Anal fissure			
subjects affected / exposed	0 / 10 (0.00%)	1 / 2 (50.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Aphthous ulcer			
subjects affected / exposed	1 / 10 (10.00%)	0 / 2 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Diarrhoea			
subjects affected / exposed	1 / 10 (10.00%)	1 / 2 (50.00%)	1 / 7 (14.29%)
occurrences (all)	1	1	1
Faeces soft			
subjects affected / exposed	1 / 10 (10.00%)	0 / 2 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Skin and subcutaneous tissue disorders			
Decubitus ulcer			
subjects affected / exposed	1 / 10 (10.00%)	0 / 2 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Dermal cyst			
subjects affected / exposed	1 / 10 (10.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Eczema			
subjects affected / exposed	1 / 10 (10.00%)	0 / 2 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Seborrhoeic dermatitis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 2 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Renal and urinary disorders			
Renal failure			
subjects affected / exposed	0 / 10 (0.00%)	1 / 2 (50.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Urinary incontinence			

subjects affected / exposed	1 / 10 (10.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Spinal deformity			
subjects affected / exposed	1 / 10 (10.00%)	0 / 2 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Infections and infestations			
Abscess limb			
subjects affected / exposed	1 / 10 (10.00%)	0 / 2 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Asymptomatic bacteriuria			
subjects affected / exposed	4 / 10 (40.00%)	0 / 2 (0.00%)	3 / 7 (42.86%)
occurrences (all)	5	0	4
Bronchitis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 2 (50.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Conjunctivitis bacterial			
subjects affected / exposed	1 / 10 (10.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Impetigo			
subjects affected / exposed	1 / 10 (10.00%)	0 / 2 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Influenza			
subjects affected / exposed	2 / 10 (20.00%)	0 / 2 (0.00%)	2 / 7 (28.57%)
occurrences (all)	2	0	2
Nasopharyngitis			
subjects affected / exposed	6 / 10 (60.00%)	1 / 2 (50.00%)	4 / 7 (57.14%)
occurrences (all)	13	1	10
Oral herpes			
subjects affected / exposed	1 / 10 (10.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Pharyngitis			
subjects affected / exposed	2 / 10 (20.00%)	0 / 2 (0.00%)	1 / 7 (14.29%)
occurrences (all)	2	0	1
Sinusitis			

subjects affected / exposed	2 / 10 (20.00%)	0 / 2 (0.00%)	1 / 7 (14.29%)
occurrences (all)	3	0	2

Non-serious adverse events	Fesoterodine 8 mg Tablet	Total of Treatment Groups	Fesoterodine 4 mg Capsule
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 2 (100.00%)	11 / 12 (91.67%)	3 / 3 (100.00%)
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	1 / 2 (50.00%)	1 / 12 (8.33%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Pyrexia			
subjects affected / exposed	1 / 2 (50.00%)	3 / 12 (25.00%)	1 / 3 (33.33%)
occurrences (all)	1	4	1
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 2 (0.00%)	1 / 12 (8.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 2 (0.00%)	1 / 12 (8.33%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 2 (0.00%)	2 / 12 (16.67%)	1 / 3 (33.33%)
occurrences (all)	0	2	1
Product issues			
Device malfunction			
subjects affected / exposed	0 / 2 (0.00%)	1 / 12 (8.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Investigations			
Urodynamics measurement abnormal			
subjects affected / exposed	0 / 2 (0.00%)	1 / 12 (8.33%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Injury, poisoning and procedural complications			
Chillblains			
subjects affected / exposed	1 / 2 (50.00%)	1 / 12 (8.33%)	0 / 3 (0.00%)
occurrences (all)	1	1	0

Nervous system disorders			
Headache			
subjects affected / exposed	1 / 2 (50.00%)	1 / 12 (8.33%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Eye disorders			
Astigmatism			
subjects affected / exposed	0 / 2 (0.00%)	1 / 12 (8.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 2 (0.00%)	1 / 12 (8.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Myopia			
subjects affected / exposed	0 / 2 (0.00%)	2 / 12 (16.67%)	2 / 3 (66.67%)
occurrences (all)	0	2	2
Strabismus			
subjects affected / exposed	0 / 2 (0.00%)	1 / 12 (8.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Visual acuity reduced			
subjects affected / exposed	1 / 2 (50.00%)	1 / 12 (8.33%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Gastrointestinal disorders			
Anal fissure			
subjects affected / exposed	1 / 2 (50.00%)	1 / 12 (8.33%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Aphthous ulcer			
subjects affected / exposed	0 / 2 (0.00%)	1 / 12 (8.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Diarrhoea			
subjects affected / exposed	1 / 2 (50.00%)	2 / 12 (16.67%)	0 / 3 (0.00%)
occurrences (all)	1	2	0
Faeces soft			
subjects affected / exposed	0 / 2 (0.00%)	1 / 12 (8.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Decubitus ulcer			
subjects affected / exposed	0 / 2 (0.00%)	1 / 12 (8.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0

Dermal cyst			
subjects affected / exposed	0 / 2 (0.00%)	1 / 12 (8.33%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Eczema			
subjects affected / exposed	0 / 2 (0.00%)	1 / 12 (8.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 12 (8.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
Renal failure			
subjects affected / exposed	1 / 2 (50.00%)	1 / 12 (8.33%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Urinary incontinence			
subjects affected / exposed	0 / 2 (0.00%)	1 / 12 (8.33%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Musculoskeletal and connective tissue disorders			
Spinal deformity			
subjects affected / exposed	0 / 2 (0.00%)	1 / 12 (8.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Abscess limb			
subjects affected / exposed	0 / 2 (0.00%)	1 / 12 (8.33%)	0 / 3 (0.00%)
occurrences (all)	0	11	0
Asymptomatic bacteriuria			
subjects affected / exposed	0 / 2 (0.00%)	4 / 12 (33.33%)	1 / 3 (33.33%)
occurrences (all)	0	5	1
Bronchitis			
subjects affected / exposed	1 / 2 (50.00%)	1 / 12 (8.33%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Conjunctivitis bacterial			
subjects affected / exposed	0 / 2 (0.00%)	1 / 12 (8.33%)	1 / 3 (33.33%)
occurrences (all)	0	2	2
Impetigo			
subjects affected / exposed	0 / 2 (0.00%)	1 / 12 (8.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0

Influenza			
subjects affected / exposed	0 / 2 (0.00%)	2 / 12 (16.67%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Nasopharyngitis			
subjects affected / exposed	1 / 2 (50.00%)	7 / 12 (58.33%)	2 / 3 (66.67%)
occurrences (all)	1	14	3
Oral herpes			
subjects affected / exposed	0 / 2 (0.00%)	1 / 12 (8.33%)	1 / 3 (33.33%)
occurrences (all)	0	2	2
Pharyngitis			
subjects affected / exposed	0 / 2 (0.00%)	2 / 12 (16.67%)	1 / 3 (33.33%)
occurrences (all)	0	2	1
Sinusitis			
subjects affected / exposed	0 / 2 (0.00%)	2 / 12 (16.67%)	1 / 3 (33.33%)
occurrences (all)	0	3	1

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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Prioritization of endpoints was based on study team's discretion.

Notes: