



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 A0221047, 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 (\leq) 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 \leq 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 (\leq) 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 \leq 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 \leq 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

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 |
|-----------------|--|

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 $<0.8 \times \text{lower limit of normal (LLN)}$; platelets $<0.5 \times \text{LLN}$ $>1.75 \times \text{upper limit of normal (ULN)}$; leukocytes $<0.6 \times \text{LLN}$ $>1.5 \times \text{ULN}$; lymphocytes, neutrophils $<0.8 \times \text{LLN}$ $>1.2 \times \text{UL}$; basophils, eosinophils, monocytes $>1.2 \times \text{ULN}$. Clinical chemistry: bilirubin, direct bilirubin $>1.5 \times \text{ULN}$; aspartate aminotransferase (AT), alanine AT, gamma glutamyl transferase, lactate dehydrogenase, alkaline phosphatase $>3.0 \times \text{ULN}$; protein, albumin $<0.8 \times \text{LLN}$ $>1.2 \times \text{ULN}$; blood urea nitrogen, creatinine $>1.3 \times \text{ULN}$; urate $>1.2 \times \text{ULN}$, sodium $<0.95 \times \text{LLN}$ $>1.05 \times \text{ULN}$; potassium, chloride, bicarbonate $<0.9 \times \text{LLN}$ $>1.1 \times \text{ULN}$; glucose $<0.6 \times \text{LLN}$ $>1.5 \times \text{ULN}$; creatine kinase $>2.0 \times \text{ULN}$. 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 (\pm 28.28) | 149.7 (\pm 38.49) | 102.3 (\pm 48.95) | 181.0 (\pm 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

| 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 Micturations 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 Micturations 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 micturations per 24 hours were calculated as the total number of micturations 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 micturations 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 (\pm 42.309) | () | () |
| Change at Week 12 | () | 15.77 (\pm 6.924) | () | () |
| Change at Week 28 | () | 4.75 (\pm 14.496) | () | () |
| Change at Final Visit | () | 4.75 (\pm 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 (\pm 42.309) | 73.42 (\pm 42.309) | | |
| Change at Week 12 | 15.77 (\pm 6.924) | 15.77 (\pm 6.924) | | |
| Change at Week 28 | 4.75 (\pm 14.496) | 4.75 (\pm 14.496) | | |
| Change at Final Visit | 4.75 (\pm 14.496) | 4.75 (\pm 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 catheterization. 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

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

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

| | | | |
|--|----------------------|--------------------|--------------------|
| subjects affected / exposed occurrences (all) | 1 / 10 (10.00%) 1 | 0 / 2 (0.00%) 0 | 0 / 7 (0.00%) 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 occurrences (all) | 0 / 2 (0.00%) 0 | 1 / 12 (8.33%) 1 | 1 / 3 (33.33%) 1 |
| Eczema subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 1 / 12 (8.33%) 1 | 0 / 3 (0.00%) 0 |
| Seborrhoeic dermatitis subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 1 / 12 (8.33%) 1 | 0 / 3 (0.00%) 0 |
| Renal and urinary disorders Renal failure subjects affected / exposed occurrences (all) | 1 / 2 (50.00%) 1 | 1 / 12 (8.33%) 1 | 0 / 3 (0.00%) 0 |
| Urinary incontinence subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 1 / 12 (8.33%) 1 | 1 / 3 (33.33%) 1 |
| Musculoskeletal and connective tissue disorders Spinal deformity subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 1 / 12 (8.33%) 1 | 0 / 3 (0.00%) 0 |
| Infections and infestations Abscess limb subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 1 / 12 (8.33%) 11 | 0 / 3 (0.00%) 0 |
| Asymptomatic bacteriuria subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 4 / 12 (33.33%) 5 | 1 / 3 (33.33%) 1 |
| Bronchitis subjects affected / exposed occurrences (all) | 1 / 2 (50.00%) 1 | 1 / 12 (8.33%) 1 | 0 / 3 (0.00%) 0 |
| Conjunctivitis bacterial subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 1 / 12 (8.33%) 2 | 1 / 3 (33.33%) 2 |
| Impetigo subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 1 / 12 (8.33%) 1 | 0 / 3 (0.00%) 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.

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|---|
| Prioritization of endpoints was based on study team's discretion. |
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Notes: