Clinical trial results:
A Phase IIb/III, multi-centre, double-blind, randomised, placebo-controlled, dose ranging study of tamsulosin hydrochloride (low, medium and high dose) as treatment in children with neuropathic bladder for three months

Due to a system error, the data reported in v1 is not correct and has been removed from public view.

Summary

EudraCT number	2006-003048-52
Trial protocol	DE BE ES IT
Global end of trial date	12 February 2009

Results information

Result version number	v2 (current)
This version publication date	02 July 2016
First version publication date	09 August 2015
Version creation reason	• Correction of full data set Data correction due to a system error in EudraCT- Results

Trial information

Trial identification

Sponsor protocol code	527.51

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00796614
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Boehringer Ingelheim
Sponsor organisation address	173 Binger Strasse, Ingelheim am Rhein, Germany, 55216
Public contact	QRPE Processes and Systems Coordination Clinical Trial Information Disclosure, Boehringer Ingelheim , +1 8002430127, clintriage.rdg@boehringer-ingelheim.com
Scientific contact	QRPE Processes and Systems Coordination Clinical Trial Information Disclosure, Boehringer Ingelheim , +1 8002430127, clintriage.rdg@boehringer-ingelheim.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?	Yes
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	12 March 2009
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	12 February 2009
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the efficacy and safety of a range of doses of tamsulosin hydrochloride as treatment in children with an elevated detrusor leak point pressure associated with a known neurological deficit (e.g., spina bifida).

This trial consisted two study periods:
Study Period I, double-blind, dose titration period of 2 weeks.
Study Period II, a double-blind maintenance treatment period of 3 months. In Period II, all patients completing the titration phase entered the 12-week maintenance treatment phase on their randomised dose. The patients stayed on this dose for the duration of the trial.

Protection of trial subjects:

Only subjects that met all the study inclusion and none of the exclusion criteria were to be entered in the study. All subjects were free to withdraw from the clinical trial at any time for any reason given. Close monitoring of all subjects was adhered to throughout the trial conduct.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	28 November 2007
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Spain: 2
Country: Number of subjects enrolled	Germany: 3
Country: Number of subjects enrolled	India: 83
Country: Number of subjects enrolled	United States: 13
Country: Number of subjects enrolled	Mexico: 20
Country: Number of subjects enrolled	Brazil: 7
Country: Number of subjects enrolled	Italy: 11
Country: Number of subjects enrolled	Russian Federation: 13
Country: Number of subjects enrolled	Korea, Democratic People's Republic of: 23
Country: Number of subjects enrolled	Philippines: 27
Country: Number of subjects enrolled	Ukraine: 13
Country: Number of subjects enrolled	South Africa: 16

Worldwide total number of subjects	231
EEA total number of subjects	16

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)	168
Adolescents (12-17 years)	63
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The trial included children from 2-16 years of age,with elevated LPP associated with a known neurologic defect(e.g., spina bifida).The 3 age strata were 2-<5 years,5-<10 years &10-16 years of age.A "Missing" category is unavailable for age group breakdown of enrolled subjects.Hence,1 subject with a missing data is added to age-category"12-17 years.

Pre-assignment

Screening details:

All subjects were screened for eligibility to participate in trial. Subjects attended specialist sites to ensure that they met all implemented inclusion/exclusion criteria. Subjects were not randomised to trial drug if any of the specific entry criteria was violated. In this study,231 subjects enrolled,162 subjects randomised &161 subjects treated.

Period 1

Period 1 title	Treatment period (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Blinding implementation details:

This trial was double blinded and to maintain the double-blind design, study medications were supplied so that the tamsulosin hydrochloride and placebo capsules were identical.The contents of each placebo capsule had an identical volume to the corresponding capsule of the same dose level of active medication.

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Subjects were orally administered to matching placebo to tamsulosin hydrochloride, with once daily by sprinkling the content of 2 capsules over a single teaspoonful (5 mL) of apple sauce or yogurt, taken 30 minutes after meal / snack (breakfast). A teaspoonful of water was taken after ingesting the applesauce or yogurt.

Arm type	Placebo
Investigational medicinal product name	Placebo (tamsulosin hydrochloride)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Subjects were orally administered to matching placebo to tamsulosin hydrochloride, with once daily by sprinkling the content of 2 capsules over a single teaspoonful (5 mL) of apple sauce or yogurt, taken 30 minutes after meal / snack (breakfast). A teaspoonful of water was taken after ingesting the applesauce or yogurt.

Arm title	tamsulosin - low dose level

Arm description:

Subjects were orally administered to low dose level (0.001 – 0.002 mg/kg) of tamsulosin hydrochloride, once daily dependent on a patient's body weight (12.5 kg -100.0 kg), by sprinkling the content of 2 capsules over a single teaspoonful (5 mL) of applesauce or yogurt, taken 30 minutes after meal / snack (breakfast). A teaspoonful of water was taken after ingesting the applesauce or yogurt.

Arm type	Experimental

Investigational medicinal product name	tamsulosin hydrochloride (0.025 mg)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Subjects were orally administered to low dose (0.025 mg) of tamsulosin hydrochloride, once daily dependent on a patient's body weight (12.5 kg – 25.0 kg), by sprinkling the content of 2 capsules over a single teaspoonful (5 mL) of applesauce or yogurt, taken 30 minutes after meal / snack (breakfast). A teaspoonful of water was taken after ingesting the applesauce or yogurt.

Investigational medicinal product name	tamsulosin hydrochloride (0.05 mg)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Subjects were orally administered to low dose (0.05 mg) of tamsulosin hydrochloride, once daily dependent on a patient's body weight (25.1 kg – 50.0 kg), by sprinkling the content of 2 capsules over a single teaspoonful (5 mL) of applesauce or yogurt, taken 30 minutes after meal / snack (breakfast). A teaspoonful of water was taken after ingesting the applesauce or yogurt.

Investigational medicinal product name	tamsulosin hydrochloride (0.1 mg)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Subjects were orally administered to low dose (0.1 mg) of tamsulosin hydrochloride, once daily dependent on a patient's body weight (50.1 kg – 100.0 kg), by sprinkling the content of 2 capsules over a single teaspoonful (5 mL) of applesauce or yogurt, taken 30 minutes after meal / snack (breakfast). A teaspoonful of water was taken after ingesting the applesauce or yogurt.

Arm title	tamsulosin - medium dose level

Arm description:

Subjects were orally administered to medium dose level (0.002 – 0.004 mg/kg) of tamsulosin hydrochloride, once daily dependent on a patient's body weight (12.5 kg -100.0 kg), by sprinkling the content of 2 capsules over a single teaspoonful (5 mL) of applesauce or yogurt, taken 30 minutes after meal / snack (breakfast). A teaspoonful of water was taken after ingesting the applesauce or yogurt. One subject randomised to tamsulosin - medium dose level was not treated. Although actual number of subjects started is 40, 39 were reported to ensure consistent reporting with baseline characteristics that includes only treated subjects.

Arm type	Experimental
Investigational medicinal product name	tamsulosin hydrochloride (0.05 mg)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Subjects were orally administered to medium dose (0.05 mg) of tamsulosin hydrochloride, once daily dependent on a patient's body weight (12.5 kg – 25.0 kg), by sprinkling the content of 2 capsules over a single teaspoonful (5 mL) of applesauce or yogurt, taken 30 minutes after meal / snack (breakfast). A teaspoonful of water was taken after ingesting the applesauce or yogurt.

Investigational medicinal product name	tamsulosin hydrochloride (0.1 mg)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Subjects were orally administered to medium dose (0.1 mg) of tamsulosin hydrochloride, once daily dependent on a patient's body weight (25.1 kg – 50.0 kg), by sprinkling the content of 2 capsules over a single teaspoonful (5 mL) of applesauce or yogurt, taken 30 minutes after meal / snack (breakfast). A teaspoonful of water was taken after ingesting the applesauce or yogurt.

Investigational medicinal product name	tamsulosin hydrochloride (0.2 mg)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Subjects were orally administered to medium dose (0.2 mg) of tamsulosin hydrochloride, once daily dependent on a patient's body weight (50.1 kg – 100.0 kg), by sprinkling the content of 2 capsules over a single teaspoonful (5 mL) of applesauce or yogurt, taken 30 minutes after meal / snack (breakfast). A teaspoonful of water was taken after ingesting the applesauce or yogurt.

Arm title	tamsulosin - high dose level

Arm description:

Subjects were orally administered to high dose level (0.004 – 0.008 mg/kg) of tamsulosin hydrochloride, once daily dependent on a patient's body weight (12.5 kg -100.0 kg), by sprinkling the content of 2 capsules over a single teaspoonful (5 mL) of applesauce or yogurt, taken 30 minutes after meal / snack (breakfast). A teaspoonful of water was taken after ingesting the applesauce or yogurt.

Arm type	Experimental
Investigational medicinal product name	tamsulosin hydrochloride (0.1 mg)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Subjects were orally administered to high dose (0.1) mg of tamsulosin hydrochloride, once daily dependent on a patient's body weight (12.5 kg – 25.0 kg), by sprinkling the content of 2 capsules over a single teaspoonful (5 mL) of applesauce or yogurt, taken 30 minutes after meal / snack (breakfast). A teaspoonful of water was taken after ingesting the applesauce or yogurt.

Investigational medicinal product name	tamsulosin hydrochloride (0.2 mg)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Subjects were orally administered to high dose (0.2 mg) of tamsulosin hydrochloride, once daily dependent on a patient's body weight (25.1 kg– 50.0 kg), by sprinkling the content of 2 capsules over a single teaspoonful (5 mL) of applesauce or yogurt, taken 30 minutes after meal / snack (breakfast). A teaspoonful of water was taken after ingesting the applesauce or yogurt.

Investigational medicinal product name	tamsulosin hydrochloride (0.4 mg)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Subjects were orally administered to high dose (0.4 mg) of tamsulosin hydrochloride, once daily dependent on a patient's body weight (50.1 kg– 100.0 kg), by sprinkling the content of 2 capsules over a single teaspoonful (5 mL) of applesauce or yogurt, taken 30 minutes after meal / snack (breakfast). A teaspoonful of water was taken after ingesting the applesauce or yogurt.

Number of subjects in period 1[1]	Placebo	tamsulosin - low dose level	tamsulosin - medium dose level
Started	41	40	39
Completed	36	36	36
Not completed	5	4	3
Consent withdrawn by subject	1	-	-
Adverse event, non-fatal	1	2	-
Lost to follow-up	2	2	1
Other than stated	1	-	-
Protocol deviation	-	-	2

Number of subjects in period 1[1]	tamsulosin - high dose level
Started	41
Completed	40
Not completed	1
Consent withdrawn by subject	1
Adverse event, non-fatal	-
Lost to follow-up	-
Other than stated	-
Protocol deviation	-

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: Baseline characteristics are based on the patients who were randomised after successfully completing the screening period and received at least one dose of the trial medication.

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Subjects were orally administered to matching placebo to tamsulosin hydrochloride, with once daily by sprinkling the content of 2 capsules over a single teaspoonful (5 mL) of apple sauce or yogurt, taken 30 minutes after meal / snack (breakfast). A teaspoonful of water was taken after ingesting the applesauce or yogurt.	
Reporting group title	tamsulosin - low dose level
Reporting group description:	
Subjects were orally administered to low dose level (0.001 – 0.002 mg/kg) of tamsulosin hydrochloride, once daily dependent on a patient's body weight (12.5 kg -100.0 kg), by sprinkling the content of 2 capsules over a single teaspoonful (5 mL) of applesauce or yogurt, taken 30 minutes after meal / snack (breakfast). A teaspoonful of water was taken after ingesting the applesauce or yogurt.	
Reporting group title	tamsulosin - medium dose level
Reporting group description:	
Subjects were orally administered to medium dose level (0.002 – 0.004 mg/kg) of tamsulosin hydrochloride, once daily dependent on a patient's body weight (12.5 kg -100.0 kg), by sprinkling the content of 2 capsules over a single teaspoonful (5 mL) of applesauce or yogurt, taken 30 minutes after meal / snack (breakfast). A teaspoonful of water was taken after ingesting the applesauce or yogurt. One subject randomised to tamsulosin - medium dose level was not treated. Although actual number of subjects started is 40, 39 were reported to ensure consistent reporting with baseline characteristics that includes only treated subjects.	
Reporting group title	tamsulosin - high dose level
Reporting group description:	
Subjects were orally administered to high dose level (0.004 – 0.008 mg/kg) of tamsulosin hydrochloride, once daily dependent on a patient's body weight (12.5 kg -100.0 kg), by sprinkling the content of 2 capsules over a single teaspoonful (5 mL) of applesauce or yogurt, taken 30 minutes after meal / snack (breakfast). A teaspoonful of water was taken after ingesting the applesauce or yogurt.	

Reporting group values	Placebo	tamsulosin - low dose level	tamsulosin - medium dose level
Number of subjects	41	40	39
Age categorical Units: Subjects			
2 to < 5 years	7	8	7
5 to < 10 years	18	17	17
10 to 16 years	16	15	15
Age continuous			
Treated set was used for this Study. Treated Set (TS): Includes all patients who were documented to have taken at least one dose of randomised treatment.			
Units: years			
arithmetic mean	8.4	8.1	8.1
standard deviation	± 3.7	± 4.2	± 3.8
Gender categorical Units: Subjects			
Female	16	18	14
Male	25	22	25

Reporting group values	tamsulosin - high dose level	Total	
Number of subjects	41	161	

Age categorical Units: Subjects			
2 to < 5 years	8	30	
5 to < 10 years	18	70	
10 to 16 years	15	61	
Age continuous			
Treated set was used for this Study. Treated Set (TS): Includes all patients who were documented to have taken at least one dose of randomised treatment.			
Units: years			
arithmetic mean	8.2		
standard deviation	± 4.3	-	
Gender categorical Units: Subjects			
Female	16	64	
Male	25	97	

End points

End points reporting groups

Reporting group title	Placebo

Reporting group description:

Subjects were orally administered to matching placebo to tamsulosin hydrochloride, with once daily by sprinkling the content of 2 capsules over a single teaspoonful (5 mL) of apple sauce or yogurt, taken 30 minutes after meal / snack (breakfast). A teaspoonful of water was taken after ingesting the applesauce or yogurt.

Reporting group title	tamsulosin - low dose level

Reporting group description:

Subjects were orally administered to low dose level (0.001 – 0.002 mg/kg) of tamsulosin hydrochloride, once daily dependent on a patient's body weight (12.5 kg -100.0 kg), by sprinkling the content of 2 capsules over a single teaspoonful (5 mL) of applesauce or yogurt, taken 30 minutes after meal / snack (breakfast). A teaspoonful of water was taken after ingesting the applesauce or yogurt.

Reporting group title	tamsulosin - medium dose level

Reporting group description:

Subjects were orally administered to medium dose level (0.002 – 0.004 mg/kg) of tamsulosin hydrochloride, once daily dependent on a patient's body weight (12.5 kg -100.0 kg), by sprinkling the content of 2 capsules over a single teaspoonful (5 mL) of applesauce or yogurt, taken 30 minutes after meal / snack (breakfast). A teaspoonful of water was taken after ingesting the applesauce or yogurt. One subject randomised to tamsulosin - medium dose level was not treated. Although actual number of subjects started is 40, 39 were reported to ensure consistent reporting with baseline characteristics that includes only treated subjects.

Reporting group title	tamsulosin - high dose level

Reporting group description:

Subjects were orally administered to high dose level (0.004 – 0.008 mg/kg) of tamsulosin hydrochloride, once daily dependent on a patient's body weight (12.5 kg -100.0 kg), by sprinkling the content of 2 capsules over a single teaspoonful (5 mL) of applesauce or yogurt, taken 30 minutes after meal / snack (breakfast). A teaspoonful of water was taken after ingesting the applesauce or yogurt.

Primary: Response defined as patients who decrease their detrusor leak point pressure (LPP) to <40 cm H2O based upon two evaluations on the same day.

End point title	Response defined as patients who decrease their detrusor leak point pressure (LPP) to <40 cm H2O based upon two evaluations on the same day.

End point description:

The primary endpoint was response to treatment defined as patients who decreased their detrusor leak point pressure (LPP) based upon two evaluations on the same day to less than 40 cm H2O at Week 14 (end of treatment).

Detrusor leak point pressure (LPP) recorded in cm H2O was obtained using a standard urodynamic technique, a cystometrogram.

Full analysis set-LPP (FAS-LPP): Includes all patients in the treated set who received at least one dose of randomised. FAS-LPP contains same patients as TS.

On treatment (OT): Consist of all on treatment data. Observations measured ≤3 days of stopping treatment was considered as on treatment. Missing data in these analyses was not replaced or imputed.

End point type	Primary

End point timeframe:

Week 14

End point values	Placebo	tamsulosin - low dose level	tamsulosin - medium dose level	tamsulosin - high dose level
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	34[1]	35[2]	33[3]	33[4]
Units: Percentage of participants				
number (not applicable)	35.3	45.7	27.3	42.4

Notes:

[1] - Full analysis set-LPP (FAS-LPP), OT

[2] - Full analysis set-LPP (FAS-LPP), OT

[3] - Full analysis set-LPP (FAS-LPP), OT

[4] - Full analysis set-LPP (FAS-LPP), OT

Statistical analyses

Statistical analysis title	tamsulosin - low dose vs. Placebo

Statistical analysis description:

Logistic regression model was used with treatment variable and three covariates: age group, concomitant use of anti-cholinergic medication and geographic region. The first two covariates were used in the stratification of the randomisation. On treatment (OT) analyses approach was used.

Comparison groups	tamsulosin - low dose level v Placebo
Number of subjects included in analysis	69
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5388
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.38
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	3.8

Statistical analysis title	tamsulosin - medium dose vs. Placebo

Statistical analysis description:

Logistic regression model was used with treatment variable and three covariates: age group, concomitant use of anti-cholinergic medication and geographic region.The first two covariates were used in the stratification of the randomisation. On treatment (OT) analyses approach was used.

Comparison groups	tamsulosin - medium dose level v Placebo
Number of subjects included in analysis	67
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.343
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.59

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.2
upper limit	1.76

Statistical analysis title	tamsulosin - high dose vs. Placebo

Statistical analysis description:

Logistic regression model was used with treatment variable and three covariates: age group, concomitant use of anti-cholinergic medication and geographic region. The first two covariates were used in the stratification of the randomisation. On treatment (OT) analyses approach was used.

Comparison groups	tamsulosin - high dose level v Placebo
Number of subjects included in analysis	67
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5209
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	3.97

Statistical analysis title	Test of Trend

Statistical analysis description:

A test of trend across the four treatment groups was performed as a secondary analysis in the proportion of responders across the dose levels using Cochran−Armitage trend test.

Comparison groups	Placebo v tamsulosin - low dose level v tamsulosin - medium dose level v tamsulosin - high dose level
Number of subjects included in analysis	135
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9436
Method	Cochran−Armitage trend test

Secondary: Change from baseline in LPP at Week 14 (end of treatment)

End point title	Change from baseline in LPP at Week 14 (end of treatment)

End point description:

Change from baseline in detrusor leak point pressure (LPP) at Week 14 (end of treatment) between each dose group and the placebo group was compared for the FAS-LPP.

End point type	Secondary

End point timeframe:

Baseline and Week 14

End point values	Placebo	tamsulosin - low dose level	tamsulosin - medium dose level	tamsulosin - high dose level
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	30[5]	32[6]	31[7]	33[8]
Units: cm H2O				
least squares mean (standard error)	-11.4 (± 4.6)	-17.6 (± 4.5)	-4.6 (± 4.4)	-14.3 (± 4.3)

Notes:

[5] - Full analysis set-LPP(FAS-LPP), OT

[6] - Full analysis set-LPP(FAS-LPP), OT

[7] - Full analysis set-LPP(FAS-LPP), OT

[8] - Full analysis set-LPP(FAS-LPP), OT

Statistical analyses

Statistical analysis title	tamsulosin - low dose vs. Placebo

Statistical analysis description:

ANCOVA model was used with covariates of age group, anti-cholinergic use at baseline and geographic region. On treatment (OT) analyses approach was used.

Comparison groups	tamsulosin - low dose level v Placebo
Number of subjects included in analysis	62
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3097
Method	ANCOVA
Confidence interval	
level	95 %
sides	2-sided
lower limit	-18.22
upper limit	5.83

Statistical analysis title	tamsulosin - medium dose vs. Placebo

Statistical analysis description:

ANCOVA model was used with covariates of age group, anti-cholinergic use at baseline and geographic region. On treatment (OT) analyses approach was used.

Comparison groups	tamsulosin - medium dose level v Placebo
Number of subjects included in analysis	61
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2676
Method	ANCOVA
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.28
upper limit	18.85

Statistical analysis title	tamsulosin - high dose vs. Placebo

Statistical analysis description:

ANCOVA model was used with covariates of age group, anti-cholinergic use at baseline and geographic region. On treatment (OT) analyses approach was used.

Comparison groups	tamsulosin - high dose level v Placebo
Number of subjects included in analysis	63
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6265
Method	ANCOVA
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.84
upper limit	8.98

Secondary: Percentage Change from baseline in LPP at Week 14 (end of treatment)

End point title	Percentage Change from baseline in LPP at Week 14 (end of treatment)

End point description:

Percent changes in detrusor leak point pressure (LPP) from baseline to the end of treatment at Week 14 between each dose group and the placebo group were compared for the FAS-LPP.

End point type	Secondary

End point timeframe:

Baseline and Week 14.

End point values	Placebo	tamsulosin - low dose level	tamsulosin - medium dose level	tamsulosin - high dose level
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	30[9]	32[10]	31[11]	33[12]
Units: Percentage change				
least squares mean (standard error)	-19.9 (± 7.3)	-27.4 (± 7.1)	-1.9 (± 7)	-23.9 (± 6.9)

Notes:

[9] - Full analysis set-LPP(FAS-LPP), OT

[10] - Full analysis set-LPP(FAS-LPP), OT

[11] - Full analysis set-LPP(FAS-LPP), OT

[12] - Full analysis set-LPP(FAS-LPP), OT

Statistical analyses

Statistical analysis title	tamsulosin - low dose vs. Placebo

Statistical analysis description:

ANCOVA model was used with covariates of age group, anti-cholinergic use at baseline and geographic region. On treatment (OT) analyses approach was used.

Comparison groups	tamsulosin - low dose level v Placebo
Number of subjects included in analysis	62
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4359
Method	ANCOVA
Confidence interval	
level	95 %
sides	2-sided
lower limit	-26.68
upper limit	11.58

Statistical analysis title	tamsulosin - medium dose vs. Placebo

Statistical analysis description:

ANCOVA model was used with covariates of age group, anti-cholinergic use at baseline and geographic region. On treatment (OT) analyses approach was used.

Comparison groups	tamsulosin - medium dose level v Placebo
Number of subjects included in analysis	61
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0658
Method	ANCOVA
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.19
upper limit	37.17

Statistical analysis title	tamsulosin - high dose vs. Placebo

Statistical analysis description:

ANCOVA model was used with covariates of age group, anti-cholinergic use at baseline and geographic region. On treatment (OT) analyses approach was used.

Comparison groups	tamsulosin - high dose level v Placebo
Number of subjects included in analysis	63
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6709
Method	ANCOVA
Confidence interval	
level	95 %
sides	2-sided
lower limit	-23.01
upper limit	14.87

Secondary: Response defined as improvement or stabilisation of hydronephrosis based upon the renal ultrasound grading at Week 14 (end of treatment) compared to baseline

End point title	Response defined as improvement or stabilisation of hydronephrosis based upon the renal ultrasound grading at Week 14 (end of treatment) compared to baseline

End point description:

Hydronephrosis response was defined as stabilisation or improvement of hydronephrosis measured by renal ultrasound at the end of treatment when compared to baseline, based on ultrasound grading.

The lower or same grade at end of treatment compared to baseline is considered an improvement or stabilization.

The Full analysis set-renal (FAS-RENAL): Includes all patients in the treated set who received at least one dose of randomised treatment and had at least one on-treatment renal ultrasound measurement.

End point type	Secondary

End point timeframe:

Baseline and Week 14.

End point values	Placebo	tamsulosin - low dose level	tamsulosin - medium dose level	tamsulosin - high dose level
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40[13]	38[14]	38[15]	40[16]
Units: Participants				
Left Kidney (N= 34, 34, 33, 40)	32	31	31	37
Right Kidney (N= 33, 34, 34, 40)	31	33	30	38

Notes:

[13] - Full analysis set-renal (FAS-RENAL), OT

[14] - Full analysis set-renal (FAS-RENAL), OT

[15] - Full analysis set-renal (FAS-RENAL), OT

[16] - Full analysis set-renal (FAS-RENAL), OT

Statistical analyses

Statistical analysis title	tamsulosin - low dose vs. Placebo(Left Kidney)

Statistical analysis description:

Patient responded to tamsulosin-low dose (LD) was compared to placebo. Logistic regression model was used with age group, anti-cholinergic use, and geographic region as covariates. On treatment (OT) analyses approach was used. The actual number of patients responded is 63 (31 for tamsulosin-LD & 32 for placebo) for Left Kidney. The pre-specified, automatically calculated number of subjects in FAS-RENAL that is provided in the statistical analysis below (78) does not reflect the actual number.

Comparison groups	tamsulosin - low dose level v Placebo
Number of subjects included in analysis	78
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5672
Method	Regression, Logistic

Statistical analysis title	tamsulosin - medium dose vs. Placebo (Left Kidney)

Statistical analysis description:

Patient responded to tamsulosin-medium dose (MD) was compared to placebo. Logistic regression model was used with age group, anti-cholinergic use, and geographic region as covariates. On treatment (OT) analyses approach was used. The actual number of patients responded is 63 (31 in tamsulosin-MD & 32 in placebo) for Left Kidney. The pre-specified, automatically calculated number of subjects in FAS-RENAL that is provided in the statistical analysis below (78) does not reflect the actual number.

Comparison groups	tamsulosin - medium dose level v Placebo
Number of subjects included in analysis	78
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8724
Method	Regression, Logistic

Statistical analysis title	tamsulosin - high dose vs. Placebo (Left Kidney)

Statistical analysis description:

Patient responded to tamsulosin-high dose (HD) was compared to placebo. Logistic regression model was used with age group, anti-cholinergic use, and geographic region as covariates. On treatment (OT) analyses approach was used. The actual number of patients responded is 69 (37 in tamsulosin-HD & 32 in placebo) for Left Kidney. The pre-specified, automatically calculated number of subjects in FAS-RENAL that is provided in the statistical analysis below (80) does not reflect the actual number.

Comparison groups	tamsulosin - high dose level v Placebo
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7674
Method	Regression, Logistic

Statistical analysis title	tamsulosin-low dose vs. Placebo (Right Kidney)

Statistical analysis description:

Patient responded to tamsulosin-low dose (LD) was compared to placebo. Logistic regression model was used with age group, anti-cholinergic use, and geographic region as covariates. On treatment (OT) analyses approach was used. The actual number of patients responded is 64 (33 for tamsulosin-LD & 31 for placebo) for Right Kidney. The pre-specified, automatically calculated number of subjects in FAS-RENAL that is provided in the statistical analysis below (78) does not reflect the actual number.

Comparison groups	tamsulosin - low dose level v Placebo
Number of subjects included in analysis	78
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5545
Method	Regression, Logistic

Statistical analysis title	tamsulosin-medium dose vs. Placebo (Right Kidney)

Statistical analysis description:

Patient responded to tamsulosin-Medium dose (MD) was compared to placebo. Logistic regression model was used with age group, anti-cholinergic use, and geographic region as covariates. On treatment (OT) analyses approach was used. The actual number of patients responded is 61(30 for tamsulosin-MD & 31

for placebo) for Right Kidney. The pre-specified, automatically calculated number of subjects in FAS-RENAL that is provided in the statistical analysis below (78) does not reflect the actual number.

Comparison groups	tamsulosin - medium dose level v Placebo
Number of subjects included in analysis	78
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4774
Method	Regression, Logistic

Statistical analysis title	tamsulosin-high dose vs. Placebo (Right Kidney)

Statistical analysis description:

Patient responded to tamsulosin-High dose (HD) was compared to placebo. Logistic regression model was used with age group, anti-cholinergic use,and geographic region as covariates. On treatment (OT) analyses approach was used. The actual number of patients responded is 69 (38 for tamsulosin-HD & 31 for placebo) for Right Kidney. The pre-specified, automatically calculated number of subjects in FAS-RENAL that is provided in the statistical analysis below (80) does not reflect the actual number.

Comparison groups	tamsulosin - high dose level v Placebo
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8626
Method	Regression, Logistic

Secondary: Response defined as improvement or stabilisation of hydroureter based upon the renal ultrasound at Week 14 (end of treatment) compared to baseline

End point title	Response defined as improvement or stabilisation of hydroureter based upon the renal ultrasound at Week 14 (end of treatment) compared to baseline

End point description:

Hydroureter response was defined as stabilisation or improvement based on change from baseline in the presence or absence of hydroureter at the end of treatment (Week 14).

Response defined as stabilization or improvement of hydroureter measured by renal ultrasound compared to baseline by treatment group (Patients are classified according to the treatment they were taking at Week 14 or end of treatment) at Week 14.

End point type	Secondary

End point timeframe:

Baseline and Week 14

End point values	Placebo	tamsulosin - low dose level	tamsulosin - medium dose level	tamsulosin - high dose level
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40[17]	38[18]	38[19]	40[20]
Units: Participants				
Left Kidney (N= 34, 34, 33, 40)	33	33	32	38
Right Kidney (N= 33, 34, 34, 40)	33	33	32	38

Notes:

[17] - Full analysis set-renal (FAS-RENAL), OT

[18] - Full analysis set-renal (FAS-RENAL), OT

[19] - Full analysis set-renal (FAS-RENAL), OT

[20] - Full analysis set-renal (FAS-RENAL), OT

Statistical analyses

Statistical analysis title	tamsulosin - low dose vs. Placebo (Left Kidney)

Statistical analysis description:

Patient responded to tamsulosin-low dose (LD) was compared to placebo. Logistic regression model was used with age group, anti-cholinergic use, and geographic region as covariates. On treatment (OT) analyses approach was used. The actual number of patients responded is 66 (33 for tamsulosin-LD & 33 for placebo) for Left Kidney. The pre-specified, automatically calculated number of subjects in FAS-RENAL that is provided in the statistical analysis below (78) does not reflect the actual number.

Comparison groups	tamsulosin - low dose level v Placebo
Number of subjects included in analysis	78
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9669
Method	Regression, Logistic

Statistical analysis title	tamsulosin - medium dose vs. Placebo (Left Kidney)

Statistical analysis description:

Patient responded to tamsulosin-medium dose (MD) was compared to placebo. Logistic regression model was used with age group, anti-cholinergic use, and geographic region as covariates. On treatment (OT) analyses approach was used. The actual number of patients responded is 65 (32 in tamsulosin-MD & 33 in placebo) for Left Kidney. The pre-specified, automatically calculated number of subjects in FAS-RENAL that is provided in the statistical analysis below (78) does not reflect the actual number.

Comparison groups	tamsulosin - medium dose level v Placebo
Number of subjects included in analysis	78
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9231
Method	Regression, Logistic

Statistical analysis title	tamsulosin - high dose vs. Placebo (Left Kidney)

Statistical analysis description:

Patient responded to tamsulosin-high dose (HD) was compared to placebo. Logistic regression model was used with age group, anti-cholinergic use, and geographic region as covariates. On treatment (OT) analyses approach was used. The actual number of patients responded is 71 (38 in tamsulosin-HD & 33 in placebo) for Left Kidney. The pre-specified, automatically calculated number of subjects in FAS-RENAL that is provided in the statistical analysis below (80) does not reflect the actual number.

Comparison groups	tamsulosin - high dose level v Placebo

Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.636
Method	Regression, Logistic

Statistical analysis title	tamsulosin - low dose vs. Placebo (Right Kidney)

Statistical analysis description:

Patient responded to tamsulosin-low dose (LD) was compared to placebo. Fisher's exact test was used for this analysis. The actual number of patients responded is 66 (33 for tamsulosin-LD & 33 for placebo) for Right Kidney. The pre-specified, automatically calculated number of subjects in FAS-RENAL that is provided in the statistical analysis below (78) does not reflect the actual number.

Comparison groups	tamsulosin - low dose level v Placebo
Number of subjects included in analysis	78
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 1
Method	Fisher exact

Statistical analysis title	tamsulosin-medium dose vs. Placebo (Right Kidney)

Statistical analysis description:

Patient responded to tamsulosin-medium dose (MD) was compared to placebo. Fisher's exact test was used for this analysis. The actual number of patients responded is 65 (32 for tamsulosin-MD & 33 for placebo) for Right Kidney. The pre-specified, automatically calculated number of subjects in FAS-RENAL that is provided in the statistical analysis below (78) does not reflect the actual number.

Comparison groups	tamsulosin - medium dose level v Placebo
Number of subjects included in analysis	78
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4925
Method	Fisher exact

Statistical analysis title	tamsulosin - high dose vs. Placebo (Right Kidney)

Statistical analysis description:

Patient responded to tamsulosin-high dose (HD) was compared to placebo. Fisher's exact test was used for this analysis. The actual number of patients responded is 71 (38 for tamsulosin-HD & 33 for placebo) for Right Kidney. The pre-specified, automatically calculated number of subjects in FAS-RENAL that is provided in the statistical analysis below (80) does not reflect the actual number.

Comparison groups	tamsulosin - high dose level v Placebo
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4977
Method	Fisher exact

Secondary: Change from baseline in urine volume at Week 14

End point title	Change from baseline in urine volume at Week 14

End point description:

Change in baseline urine volumes obtained by catheterisation as recorded in catheterisation diary at Week 14.

The Full analysis set-catheter (FAS-CATH): Includes all patients in the treated set who received at least one dose of randomised treatment, were on a catheterisation regimen, and had at least one on-treatment catheterisation assessment.

End point type	Secondary

End point timeframe:

Baseline and Week 14

End point values	Placebo	tamsulosin - low dose level	tamsulosin - medium dose level	tamsulosin - high dose level
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24[21]	18[22]	16[23]	21[24]
Units: mL				
least squares mean (standard error)	-2.3 (± 14)	-32.2 (± 15.5)	4.4 (± 16.3)	3.3 (± 14.2)

Notes:

[21] - Full analysis set-catheter (FAS-CATH), OT

[22] - Full analysis set-catheter (FAS-CATH), OT

[23] - Full analysis set-catheter (FAS-CATH), OT

[24] - Full analysis set-catheter (FAS-CATH), OT

Statistical analyses

Statistical analysis title	tamsulosin - low dose vs. Placebo

Statistical analysis description:

ANCOVA model was used with age group, anti-cholinergic use, and geographic region as covariates. On treatment (OT) analyses approach was used.

Comparison groups	tamsulosin - low dose level v Placebo
Number of subjects included in analysis	42
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1373
Method	ANCOVA
Confidence interval	
level	95 %
sides	2-sided
lower limit	-69.66
upper limit	9.78

Statistical analysis title	tamsulosin - medium dose vs. Placebo

Statistical analysis description:

ANCOVA model was used with age group, anti-cholinergic use, and geographic region as covariates. On treatment (OT) analyses approach was used.

Comparison groups	tamsulosin - medium dose level v Placebo
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.744
Method	ANCOVA
Confidence interval	
level	95 %
sides	2-sided
lower limit	-34.26
upper limit	47.74

Statistical analysis title	tamsulosin - high dose vs. Placebo

Statistical analysis description:

ANCOVA model was used with age group, anti-cholinergic use, and geographic region as covariates. On treatment (OT) analyses approach was used.

Comparison groups	tamsulosin - high dose level v Placebo
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7703
Method	ANCOVA
Confidence interval	
level	95 %
sides	2-sided
lower limit	-32.63
upper limit	43.88

Secondary: Change from baseline in number of times patient was wet at catheterisation

End point title	Change from baseline in number of times patient was wet at catheterisation

End point description:

Change from baseline in number of times patient was wet at time of catheterisation as recorded in catheterisation diary.

End point type	Secondary

End point timeframe:

Baseline and Week 14.

End point values	Placebo	tamsulosin - low dose level	tamsulosin - medium dose level	tamsulosin - high dose level
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24[25]	18[26]	16[27]	21[28]
Units: Participants				
least squares mean (standard error)	0.3 (± 0.8)	-1.7 (± 0.9)	0 (± 0.9)	-0.4 (± 0.8)

Notes:

[25] - Full analysis set-catheter (FAS-CATH), OT

[26] - Full analysis set-catheter (FAS-CATH), OT

[27] - Full analysis set-catheter (FAS-CATH), OT

[28] - Full analysis set-catheter (FAS-CATH), OT

Statistical analyses

Statistical analysis title	tamsulosin - low dose vs. Placebo

Statistical analysis description:

ANCOVA model was used with age group, anti-cholinergic use, and geographic region as covariates. On treatment (OT) analyses approach was used.

Comparison groups	tamsulosin - low dose level v Placebo
Number of subjects included in analysis	42
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0808
Method	ANCOVA
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.34
upper limit	0.26

Statistical analysis title	tamsulosin - medium dose vs. Placebo

Statistical analysis description:

ANCOVA model was used with age group, anti-cholinergic use, and geographic region as covariates. On treatment (OT) analyses approach was used.

Comparison groups	tamsulosin - medium dose level v Placebo
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8244
Method	ANCOVA
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.64
upper limit	2.11

Statistical analysis title	tamsulosin - high dose vs. Placebo

Statistical analysis description:

ANCOVA model was used with age group, anti-cholinergic use, and geographic region as covariates. On treatment (OT) analyses approach was used.

Comparison groups	tamsulosin - high dose level v Placebo
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5045
Method	ANCOVA
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.96
upper limit	1.47

Secondary: Number of participants with Clinically Relevant Abnormalities for Physical Examination, Vital Signs/Orthostatic testing,Electorocardiogram (ECG), Laboratory Values, Urinalysis and Cognitive Testing.

End point title	Number of participants with Clinically Relevant Abnormalities for Physical Examination, Vital Signs/Orthostatic testing,Electorocardiogram (ECG), Laboratory Values, Urinalysis and Cognitive Testing.

End point description:

Number of participants with Clinically Relevant Abnormalities for Physical Examination, Vital Signs/Orthostatic testing (blood pressure, pulse and respiratory rate), Electrocardiogram (ECG), Laboratory Values inclusive of hormonal assays, visual acuity, Cognitive Testing, Occurrence of treatment emergent adverse events (AEs), Premature discontinuation of study drug due to AEs and Urinalysis.

Relevant findings or worsening of baseline conditions were reported as adverse events (AEs).

Treated Set (TS). All subjects began treatment with their low dose and then they were titrated to their randomised medium or high dose. Therefore some of the subjects were counted more than once for having reported adverse events with different doses of the study.

End point type	Secondary

End point timeframe:

From first drug administration until 28 days after last study drug administration, upto 160 days

End point values	Placebo	tamsulosin - low dose level	tamsulosin - medium dose level	tamsulosin - high dose level
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18[29]	39[30]	24[31]	15[32]
Units: Participants				
Occurrence of treatment emergent AEs	2	4	1	2
Premature discontinuation of study drug due to AEs	1	2	0	0
Sinus tachycardia	0	0	0	1

Notes:

[29] - Treated Set (TS)

[30] - Treated Set (TS)

[31] - Treated Set (TS)

[32] - Treated Set (TS)

Statistical analyses

No statistical analyses for this end point

Secondary: Post void residual volume at Week 14

End point title	Post void residual volume at Week 14

End point description:

Median change from baseline to Week 14 in post void residual (mL) by study treatment.

Treated Set (TS). Number of particiapants Analysed are the number of participants whose data were available for this endpoint.

End point type	Secondary

End point timeframe:

Baseline and Week 14.

End point values	Placebo	tamsulosin - low dose level	tamsulosin - medium dose level	tamsulosin - high dose level
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	31[33]	36[34]	34[35]	38[36]
Units: mL				
median (standard deviation)	3 (± 80.28)	-19 (± 66.4)	-1.5 (± 92.33)	0 (± 58.67)

Notes:

[33] - Treated Set (TS)

[34] - Treated Set (TS)

[35] - Treated Set (TS)

[36] - Treated Set (TS)

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From first drug administration until 28 days after last study drug administration, upto 160 days.

Adverse event reporting additional description:

All subjects began treatment with their low dose and then they were titrated to their randomised medium or high dose. Therefore some of the subjects were counted more than once for having reported adverse events with different doses of the study.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	11.1

Reporting groups

Reporting group title	Placebo

Reporting group description:

Subjects were orally administered to matching placebo to tamsulosin hydrochloride, with once daily by sprinkling the content of 2 capsules over a single teaspoonful (5 mL) of apple sauce or yogurt, taken 30 minutes after meal / snack (breakfast). A teaspoonful of water was taken after ingesting the applesauce or yogurt.

Reporting group title	tamsulosin - low dose level

Reporting group description:

Subjects were orally administered to low dose level (0.001 – 0.002 mg/kg) of tamsulosin hydrochloride, once daily dependent on a patient's body weight (12.5 kg -100.0 kg), by sprinkling the content of 2 capsules over a single teaspoonful (5 mL) of applesauce or yogurt, taken 30 minutes after meal / snack (breakfast). A teaspoonful of water was taken after ingesting the applesauce or yogurt.

Reporting group title	tamsulosin - medium dose level

Reporting group description:

Subjects were orally administered to medium dose level (0.002 – 0.004 mg/kg) of tamsulosin hydrochloride, once daily dependent on a patient's body weight (12.5 kg -100.0 kg), by sprinkling the content of 2 capsules over a single teaspoonful (5 mL) of applesauce or yogurt, taken 30 minutes after meal / snack (breakfast). A teaspoonful of water was taken after ingesting the applesauce or yogurt. One subject randomised to tamsulosin - medium dose level was not treated. Although actual number of subjects started is 40, 39 were reported to ensure consistent reporting with baseline characteristics that includes only treated subjects.

Reporting group title	tamsulosin - high dose level

Reporting group description:

Subjects were orally administered to high dose level (0.004 – 0.008 mg/kg) of tamsulosin hydrochloride, once daily dependent on a patient's body weight (12.5 kg -100.0 kg), by sprinkling the content of 2 capsules over a single teaspoonful (5 mL) of applesauce or yogurt, taken 30 minutes after meal / snack (breakfast). A teaspoonful of water was taken after ingesting the applesauce or yogurt.

Serious adverse events	Placebo	tamsulosin - low dose level	tamsulosin - medium dose level
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 41 (2.44%)	1 / 120 (0.83%)	0 / 80 (0.00%)
number of deaths (all causes)	0	1	0
number of deaths resulting from adverse events	0	1	0
Injury, poisoning and procedural complications			
Shunt malfunction			

subjects affected / exposed	1 / 41 (2.44%)	0 / 120 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Haematoma			
subjects affected / exposed	1 / 41 (2.44%)	0 / 120 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Death			
subjects affected / exposed	0 / 41 (0.00%)	1 / 120 (0.83%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0

Serious adverse events	tamsulosin - high dose level		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 40 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Injury, poisoning and procedural complications			
Shunt malfunction			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Death			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Placebo	tamsulosin - low dose level	tamsulosin - medium dose level
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 41 (31.71%)	19 / 120 (15.83%)	14 / 80 (17.50%)
Nervous system disorders			
Headache			
subjects affected / exposed	6 / 41 (14.63%)	1 / 120 (0.83%)	3 / 80 (3.75%)
occurrences (all)	6	1	3
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	3 / 41 (7.32%)	0 / 120 (0.00%)	0 / 80 (0.00%)
occurrences (all)	3	0	0
Abdominal pain			
subjects affected / exposed	6 / 41 (14.63%)	1 / 120 (0.83%)	1 / 80 (1.25%)
occurrences (all)	8	1	1
Vomiting			
subjects affected / exposed	5 / 41 (12.20%)	2 / 120 (1.67%)	4 / 80 (5.00%)
occurrences (all)	5	2	4
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 41 (0.00%)	1 / 120 (0.83%)	5 / 80 (6.25%)
occurrences (all)	0	1	5
Infections and infestations			
Influenza			
subjects affected / exposed	3 / 41 (7.32%)	3 / 120 (2.50%)	1 / 80 (1.25%)
occurrences (all)	3	3	1
Nasopharyngitis			
subjects affected / exposed	1 / 41 (2.44%)	5 / 120 (4.17%)	4 / 80 (5.00%)
occurrences (all)	1	6	5
Urinary tract infection			

subjects affected / exposed	4 / 41 (9.76%)	8 / 120 (6.67%)	2 / 80 (2.50%)
occurrences (all)	4	10	2

Non-serious adverse events	tamsulosin - high dose level		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 40 (20.00%)		
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences (all)	1		
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Abdominal pain			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Vomiting			
subjects affected / exposed	3 / 40 (7.50%)		
occurrences (all)	4		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Influenza			
subjects affected / exposed	2 / 40 (5.00%)		
occurrences (all)	2		
Nasopharyngitis			
subjects affected / exposed	4 / 40 (10.00%)		
occurrences (all)	8		
Urinary tract infection			
subjects affected / exposed	5 / 40 (12.50%)		
occurrences (all)	5		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported