Clinical trial results:
Urodynamic evaluation by pressure flow urodynamic study of the new 1A-adrenoceptor antagonist silodosin 8 mg qd in patients with benign prostatic obstruction. Explorative, single-arm, phase IV clinical study.

Summary

EudraCT number	2015-002277-38
Trial protocol	IT
Global end of trial date	16 March 2017

Results information

Result version number	v1 (current)
This version publication date	15 April 2018
First version publication date	15 April 2018

Trial information

Trial identification

Sponsor protocol code	KMD3213ITCL0477

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Recordati SPA
Sponsor organisation address	Via Civitali, 1, Milan, Italy, 20148
Public contact	Direzione Medica, Recordati S.p.A., +39 0248787456, casi.m@recordati.it
Scientific contact	Direzione Medica, Recordati S.p.A., +39 0248787456, casi.m@recordati.it

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?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	20 June 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	16 March 2017
Global end of trial reached?	Yes
Global end of trial date	16 March 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of the study is to evaluate the effects of silodosin on the change from baseline in Bladder Outlet Obstruction Index (BOOI).

Protection of trial subjects:

None required

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 November 2015
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	Italy: 30
Worldwide total number of subjects	30
EEA total number of subjects	30

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)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	16
From 65 to 84 years	14
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Screening period of up to 1 week of duration.

Period 1

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

Arms

Arm title	Silodosin 8 mg

Arm description:

the subjects fulfilling all the selection criteria entered a 8-week, open-label, active treatment phase with silodosin 8 mg

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

Dosage and administration details:

Silodosin 8 mg oad per oral route

Number of subjects in period 1	Silodosin 8 mg
Started	30
Completed	30

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial

Reporting group description:

Men at least 50 years of age, with a diagnosis of presence of LUTS, with bladder outlet obstruction (BOO) associated with BPH, waiting for surgical treatment, were evaluated in this clinical study.

Reporting group values	Overall trial	Total	
Number of subjects	30	30	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	16	16	
From 65-84 years	14	14	
85 years and over	0	0	
Age continuous Units: years			
arithmetic mean	63.1		
standard deviation	± 9.2	-	
Gender categorical Units: Subjects			
Female	0	0	
Male	30	30	

End points

End points reporting groups

Reporting group title	Silodosin 8 mg

Reporting group description:

the subjects fulfilling all the selection criteria entered a 8-week, open-label, active treatment phase with silodosin 8 mg

Primary: Change from baseline in Bladder Outlet Obstruction Index (BOOI)

End point title	Change from baseline in Bladder Outlet Obstruction Index (BOOI)[1]

End point description:

End point type	Primary

End point timeframe:

Change from baseline after 8 weeks of treatment with Silodosin 8 mg

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: Only descriptive statistics have been performed for this study. No inferential statistical analysis has been performed.

End point values	Silodosin 8 mg			
Subject group type	Reporting group			
Number of subjects analysed	30			
Units: Score				
arithmetic mean (standard deviation)	-31.4 (± 22.0)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: AEs were documented from Visit 1 up to the final visit	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	19
Reporting groups	
Reporting group title	Treatment Emergent AEs

Reporting group description: -

Serious adverse events	Treatment Emergent AEs		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 30 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 4 %

Non-serious adverse events	Treatment Emergent AEs		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	11 / 30 (36.67%)		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Fatigue			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Reproductive system and breast disorders			
Retrograde ejaculation			
subjects affected / exposed	8 / 30 (26.67%)		
occurrences (all)	8		
Respiratory, thoracic and mediastinal			

disorders Nasal congestion subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 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

None reported