Clinical trial results:
Effectiveness of Silodosin in Medical Expulsive Therapy for Ureteral Pelvic Stone From 4 to 10 mm.

Summary

EudraCT number	2013-003328-35
Trial protocol	FR
Global end of trial date	01 December 2015

Results information

Result version number	v1 (current)
This version publication date	13 August 2022
First version publication date	13 August 2022

Trial information

Trial identification

Sponsor protocol code	CHD062-13

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02090439
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Centre Hospitalier Départemental Vendée
Sponsor organisation address	Boulevard Stéphane MOREAU, Visioconférence, France, 85925
Public contact	MOREAU Chloé, Centre Hospitalier Départemental Vendée, +33 0251446327, chloe.moreau@ght85.fr
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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	27 May 2016
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	01 December 2015
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

Increase in the rate of spontaneous expulsion of pelvic stones from 4 to 10 mm in the Silodosine group compared to the reference group

Protection of trial subjects:

All adverse events or reactions (except those specified in the protocol), whether expected or unexpected, serious or not, were collected in the eCRF.
The follow-up of events or adverse reactions, serious or not, was ensured until resolution or consolidation.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 July 2014
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy
Long term follow-up duration	1 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	France: 8
Worldwide total number of subjects	8
EEA total number of subjects	8

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)	8

From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

8 patients were screened for inclusion

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Standard treatment

Arm description:

Analgesics, non-steroidal anti-inflammatory drugs and control of fluid intake.

Arm type	Active comparator
Investigational medicinal product name	Analgesics
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

7 days of paracetamol

Investigational medicinal product name	Non-steroidal anti-inflammatory
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

7 days of ketoprofen

Arm title	Standard treatment associated with Urorec

Arm description:

Standard treatment and Urorec for 14 days then 14 days of Urorec alone:
- 7 days of Urorec + paracetamol + ketoprofen + fluid control
- then 7 days of Urorec + paracetamol + fluid control
- then 14 days of Urorec + fluid control

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

Dosage and administration details:

8 mg/g - per day

Investigational medicinal product name	Analgesics
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details: 7 days of paracetamol	
Investigational medicinal product name	Non-steroidal anti-inflammatory
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details: 7 days of ketoprofen	

Number of subjects in period 1	Standard treatment	Standard treatment associated with Urorec
Started	4	4
Inclusion	4	4
J14 - intermediate visit	4	3
J28 - intermediate visit	4	3
J32 - End of study (telephone contact)	4	3
Completed	4	3
Not completed	0	1
Protocol deviation	-	1

Baseline characteristics

Reporting groups	
Reporting group title	Standard treatment
Reporting group description:	
Analgesics, non-steroidal anti-inflammatory drugs and control of fluid intake.	
Reporting group title	Standard treatment associated with Urorec
Reporting group description:	
Standard treatment and Urorec for 14 days then 14 days of Urorec alone: - 7 days of Urorec + paracetamol + ketoprofen + fluid control - then 7 days of Urorec + paracetamol + fluid control - then 14 days of Urorec + fluid control	

Reporting group values	Standard treatment	Standard treatment associated with Urorec	Total
Number of subjects	4	4	8
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	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	4	4	8
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	40.75	40.75	
standard deviation	± 8.54	± 9.11	-
Gender categorical Units: Subjects			
Female	1	0	1
Male	3	4	7

End points

End points reporting groups

Reporting group title	Standard treatment
Reporting group description:	
Analgesics, non-steroidal anti-inflammatory drugs and control of fluid intake.	

Reporting group title	Standard treatment associated with Urorec
Reporting group description:	
Standard treatment and Urorec for 14 days then 14 days of Urorec alone: - 7 days of Urorec + paracetamol + ketoprofen + fluid control - then 7 days of Urorec + paracetamol + fluid control - then 14 days of Urorec + fluid control	

Primary: Spontaneous expulsion of the pelvic stone

End point title	Spontaneous expulsion of the pelvic stone[1]
End point description:	
Lithiasic elimination will be proven by : -a stone brought by the patient to the consultation and analyzed by infrared spectrophotometry (SPIR), in case of a single stone at inclusion. - a stone brought by the patient, with proof of elimination of the single pelvic stone by ASP +/- control scanner, in the case of pelvic stone associated with other calcareous stones at inclusion. -if the stone could not be recovered, a non-injection abdominal CT scan with no stone at D28.	

End point type	Primary
End point timeframe:	
28 days	

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: The study was stopped prematurely (recruitment difficulties). No statistical analysis was performed.

End point values	Standard treatment	Standard treatment associated with Urorec		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[2]	0[3]		
Units: Yes or no				

Notes:

[2] - Premature termination of the study no statistical analysis was performed

[3] - Premature termination of the study no statistical analysis was performed

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From the date the consent is signed until D32 (+/-1 day), i.e. 3 to 5 days after the last treatment.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	19

Reporting groups

Reporting group title	Standard support

Reporting group description:

Analgesics, non-steroidal anti-inflammatory drugs and control of water intake (14 days of treatment):
- 7 days of paracetamol + ketoprofen + water intake control
- Then 7 days of paracetamol + control of water intake.

Reporting group title	Standard support associated with Urorec

Reporting group description:

Standard treatment and Urorec for 14 days and then 14 days of Urorec alone:
- 7 days of Urorec + paracetamol + ketoprofen + water intake control
- then 7 days of Urorec + paracetamol + water intake control
- then 14 days of Urorec + water intake control

Serious adverse events	Standard support	Standard support associated with Urorec	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Renal and urinary disorders			
Urethral pain			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Standard support	Standard support associated with Urorec	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 4 (25.00%)	3 / 4 (75.00%)	
Cardiac disorders			

Palpitations			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	1	
Nervous system disorders			
Dizziness			
subjects affected / exposed	1 / 4 (25.00%)	1 / 4 (25.00%)	
occurrences (all)	2	2	
Somnolence			
subjects affected / exposed	1 / 4 (25.00%)	1 / 4 (25.00%)	
occurrences (all)	1	1	
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	
occurrences (all)	1	0	
Pain			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	0 / 4 (0.00%)	2 / 4 (50.00%)	
occurrences (all)	0	2	
Abdominal pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	1	
Diarrhoea			
subjects affected / exposed	0 / 4 (0.00%)	2 / 4 (50.00%)	
occurrences (all)	0	2	
Dry mouth			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	1	
Vomiting			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	
occurrences (all)	2	0	
Reproductive system and breast disorders			
Retrograde ejaculation			

subjects affected / exposed	0 / 4 (0.00%)	2 / 4 (50.00%)	
occurrences (all)	0	2	
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	
occurrences (all)	1	0	
Haematuria			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
03 July 2014	Update from the co-investigators at CHD Vendee.
30 October 2014	Updated inclusion criteria: inclusion of patients with a single pelvic ureteral stone with a transverse diameter of 4 to 10 mm, with or without calcareous (non-obstructive) calculi, but without other ureteral stones.
11 April 2015	Update from the co-investigators at CHD Vendee.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
01 December 2015	The very sustained activity of the urology department, combined with the difficulty in accessing low-dose spiral scanners in the CHD, as well as the random participation of the emergency team in recruitment due to the lack of presence of the principal investigator (a very important clinical activity) contributed to this failure. Protocol writing and safety were not an issue.	-

Notes:

Limitations and caveats

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

The study was prematurely stopped with only 8 patients included out of 160 planned due to organizational and recruitment problems.
No risk related to protocol treatment was identified.
No statistical analysis was performed.

Notes: