Clinical trial results:
Pharmacological relaxation of the ureter when using access sheaths during ureterorenoscopy

Summary

EudraCT number	2013-004475-13
Trial protocol	DK
Global end of trial date	13 January 2016

Results information

Result version number	v1 (current)
This version publication date	23 April 2020
First version publication date	23 April 2020

Trial information

Trial identification

Sponsor protocol code	13.031

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Urological Research Center
Sponsor organisation address	Beriderbakken 4, Vejle, Denmark, 7100
Public contact	Søren Kissow Lildal, Urological Research Center, soerlild@rm.dk
Scientific contact	Søren Kissow Lildal, Urological Research Center, soerlild@rm.dk
Sponsor organisation name	Urological Research Center
Sponsor organisation address	Beriderbakken 4, Vejle, Denmark, 7100
Public contact	Palle Oster, Urological Research Center, Palle.Joern.Osther@rsyd.dk
Scientific contact	Palle Oster, Urological Research Center, Palle.Joern.Osther@rsyd.dk

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	30 December 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	13 January 2016
Global end of trial reached?	Yes
Global end of trial date	13 January 2016
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To investigate if addition of isoprenaline to the irrigation fluid makes it possible to insert an access sheath in the ureter of patients were insertion was impossible because of ureteral resistance.

Protection of trial subjects:

The subjects were treated intraoperatively under full anaesthesia. The treatment does not likely cause any pain or discomfort. All patients were observed during perioperative admission and treated with regular relief of pain postoperatively if necessary as standard for this type of operation.

Background therapy:

Endoscopical treatment of urinary tract stones.

Evidence for comparator:

The comparator was saline irrigation. Saline irrigation is standard for this type of operation.

Actual start date of recruitment	01 March 2014
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	Denmark: 10
Worldwide total number of subjects	10
EEA total number of subjects	10

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)	7
From 65 to 84 years	3

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subjects were recruited from august 2014 to january 2016 in the region of Southern Denmark. The study was terminated prematurely due to a lack of subjects.

Pre-assignment

Screening details:

Inclusion criteria:

Indication for diagnostic or therapeutic ureterorenoscopy.
Men and women > 18 years

Exclusion criteria:

Known malignancies in the urinary tract
New found malignancy during operation
Allergy to isoprenaline

148 screened, 38 eligible, 10 included
Subject were finally included during operation with written consent

Period 1

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

Blinding implementation details:

During operation the subject was included for randomization and treatment if there was a subjective resistance to insertion of the ureteral access sheath, evaluated by the surgeon. An OR nurse and a controller outside the OR room would the break a sealed envelope containing a pre-randomized treatment, either usual saline or saline with isoprenaline and prepare the irrigation fluid and bring it to the OR. The envelope would afterwards be sealed again until the end of the study.

Arms

Are arms mutually exclusive?	Yes
Arm title	Saline

Arm description:

Subjects randomized to regular endoscopic irrigation with saline

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Isoprenaline

Arm description:

Regular saline irrigation fluid with added isoprenaline

Arm type	Experimental
Investigational medicinal product name	Isoprenaline
Investigational medicinal product code	ISO
Other name	
Pharmaceutical forms	Injection
Routes of administration	Local use

Dosage and administration details:

Isoprenaline 0,1 µg/ml Nacl irrigation fluid for irrigation during endoscopy in the upper urinary tract

Number of subjects in period 1	Saline	Isoprenaline
Started	5	5
Completed	5	5

Baseline characteristics

Reporting groups	
Reporting group title	Saline
Reporting group description:	
Subjects randomized to regular endoscopic irrigation with saline	
Reporting group title	Isoprenaline
Reporting group description:	
Regular saline irrigation fluid with added isoprenaline	

Reporting group values	Saline	Isoprenaline	Total
Number of subjects	5	5	10
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)			0
Adolescents (12-17 years)			0
Adults (18-64 years)			0
From 65-84 years			0
85 years and over			0
Age continuous			
Age			
Units: years			
median	58.2	55.6	
full range (min-max)	52 to 66	27 to 67	-
Gender categorical			
Units: Subjects			
Female	3	2	5
Male	2	3	5

End points

End points reporting groups

Reporting group title	Saline
Reporting group description:	
Subjects randomized to regular endoscopic irrigation with saline	
Reporting group title	Isoprenaline
Reporting group description:	
Regular saline irrigation fluid with added isoprenaline	

Primary: Effect of isoprenaline on ureteral access sheath insertion success

End point title	Effect of isoprenaline on ureteral access sheath insertion success[1]
End point description:	
End point type	Primary
End point timeframe:	
Success of insertion recorded during operation immediately after irrigation tested fluid.	

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 trial was no completed and therefore no statistical analysis can be performed as the number of included subjects is to small compared to what is necessary from power calculations.

End point values	Saline	Isoprenaline		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	5		
Units: number of subjects				
Success of insertion after irrigation	0	1		
No success of insertion after irrigation	5	4		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

Peroperatively by anesthesiology staff, postoperatively during admission by patient or ward staff or in the following period without timeframe by patient if any suspicious effects arise.

Adverse event reporting additional description:

Adverse effects would be changes of pulse or blodpressure and related symptoms to this such as: Headache, dizziness, tremor, palpitations, tachycardia, angina pectoris, flushing, nausea, vomiting, hypokalaemia.

Half life of interventional products is only a few minutes. Adverse effects are thus not to be expected after patient discharge.

Assessment type	Non-systematic

Dictionary used

Dictionary name	SAR/SUSAR
Dictionary version	1

Frequency threshold for reporting non-serious adverse events: 1 %

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: No adverse effects were reported in this study.

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.

The study was terminated before completion du to limited number of patients eligible for inclusion. 10 of 22 planned patients were included and completed. No adverse effects were reported..

Notes: