Clinical trial results:
Ultrasoundguided Transmuscular Quadratus Lumborum(TQL) block for percutaneous nephrolithotomy (PNL) - a randomized controlled trial

Summary

EudraCT number	2015-004770-16
Trial protocol	DK
Global end of trial date	30 November 2017

Results information

Result version number	v1 (current)
This version publication date	18 December 2019
First version publication date	18 December 2019

Trial information

Trial identification

Sponsor protocol code	PNL_protocol_v01

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Zealand university hospital Roskilde
Sponsor organisation address	Sygehus vej 10, Roskilde, Denmark, 4000
Public contact	Jens Børglum, Dept of Anest. Copenhagen University Hospital - Roskilde, +45 30700120, jedn@regionsjaelland.dk
Scientific contact	Jens Børglum, Dept of Anest. Copenhagen University Hospital - Roskilde, +45 30700120, jedn@regionsjaelland.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	01 April 2018
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	30 November 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate whether a unilateral USG TQL block can reduce opioid consumption with clinical significance in PNL-patients.

Protection of trial subjects:

All patients received thoroughly information prior to inclusion. They all received a PCA pump in the postoperative period

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 August 2016
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	Denmark: 60
Worldwide total number of subjects	60
EEA total number of subjects	60

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)	43
From 65 to 84 years	17
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

All patient scheduled for elective PNL operation were invited to participate in the study.the patients were screened for inclusion and exclusion criteria. Thereafter the patients received oral and written information prior to enrollment.

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	Investigator, Monitor, Subject, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Active

Arm description:

Unilateral TQL block with 0.75% ropivacaine 30 ml

Arm type	Active comparator
Investigational medicinal product name	Ropivacaine
Investigational medicinal product code	45010
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Other use

Dosage and administration details:

30 ml 0.75% ropivacain injected between QL and PM muscle

Arm title	Control

Arm description:

Received a TQL block with 30 ml of saline

Arm type	Placebo
Investigational medicinal product name	Sodium chloride
Investigational medicinal product code	B05BB01
Other name	Saline
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Other use

Dosage and administration details:

30 ml saline 0.9% injected between QL and PM muscle

Number of subjects in period 1	Active	Control
Started	30	30
Completed	25	26
Not completed	5	4
Physician decision	4	3
Consent withdrawn by subject	1	-
staff strike	-	1

Baseline characteristics

Reporting groups	
Reporting group title	Active
Reporting group description:	
Unilateral TQL block with 0.75% ropivacaine 30 ml	
Reporting group title	Control
Reporting group description:	
Received a TQL block with 30 ml of saline	

Reporting group values	Active	Control	Total
Number of subjects	30	30	60
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 Units: years			
arithmetic mean	58.5	61.7	
full range (min-max)	29 to 82	34 to 83	-
Gender categorical Units: Subjects			
Female	14	15	29
Male	16	15	31

End points

End points reporting groups	
Reporting group title	Active
Reporting group description: Unilateral TQL block with 0.75% ropivacaine 30 ml	
Reporting group title	Control
Reporting group description: Received a TQL block with 30 ml of saline	

Primary: OME 0-6 postoperative hours	
End point title	OME 0-6 postoperative hours
End point description:	
End point type	Primary
End point timeframe: 0-6 hours	

End point values	Active	Control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	25	26		
Units: mg	7	90		

Statistical analyses

Statistical analysis title	t- test
Comparison groups	Control v Active
Number of subjects included in analysis	51
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	t-test, 2-sided

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

24 hours

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	10.0

Reporting groups

Reporting group title	Any events
Reporting group description: -	
Reporting group title	Overall
Reporting group description: -	

Serious adverse events	Any events	Overall	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 58 (0.00%)	0 / 58 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

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

Non-serious adverse events	Any events	Overall	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 58 (0.00%)	0 / 58 (0.00%)	

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: There were no adverse events reported regarding ropivacaine

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

Online references

http://www.ncbi.nlm.nih.gov/pubmed/31153628