Clinical trial results:
Ultrasound-guided Transmuscular Quadratus Lumborum block for elective caesarean section. A double blind, randomized, placebo controlled trial.

Summary

EudraCT number	2016-004594-41
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	2016-1

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	Sygehusvej 10, Roskilde, Denmark, 4000
Public contact	Jens Børglum, Dept. of Anaesthesia - Zealand University Hospital, Roskilde, +45 30700120, jens.borglum@gmail.com
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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	01 May 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 investigate the efficacy of the TQL block (reduction in use of opioids in the first 24 postoperative hours) vs. Placebo in patients undergoing elective Caesarean Section.

Protection of trial subjects:

All participants received oral and written information before decision on participation. All participants recevived the standard pain tratment for their cesarean section. On top of the standard treatment, the intervention was made in the immediate postoperative setting, when their spinal anaesthesia was still intact, so no further discomfort was experienced.
If/when participants would feel pain they would have an intravenous (IV) patient-controlled-analgesia device attached to an IV-line for immediate pain relief.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 March 2017
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: 72
Worldwide total number of subjects	72
EEA total number of subjects	72

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)	72
From 65 to 84 years	0

85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

All parturients scheduled for elective cesarean section at our institution (Zealand University Hospital, Roskilde) were invited to particpate in the study. Inclusion/exclusion criteria were assessed and oral and written information was given .

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, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Active

Arm description:

Bilateral transmuscular quadratus lumborum block with 2 x 30 ml 0.375% ropivacain

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

Dosage and administration details:

Participants would receive 2 x 30 ml of the active substance.
Ropivacaine 0.75% was diluted in a 1:1 ratio with saline in order to achieve a 0.375% concentration.
2 x 30 ml of the 0.375% concentration were injected, 30 ml on each side.

Arm title	Control

Arm description:

Bilat. transmuscular quadratus lumborum block with 2 x 30 ml saline.

Arm type	Placebo
Investigational medicinal product name	Saline
Investigational medicinal product code	B05BB01
Other name	NaCl, physiologic sodium-chloride
Pharmaceutical forms	Solution for injection
Routes of administration	Other use

Dosage and administration details:

2 x 30 ml Saline as bilateral transmuscular quadratus lumborum block.

Number of subjects in period 1	Active	Control
Started	36	36
Completed	34	34
Not completed	2	2
Physician decision	1	-
Lost to follow-up	1	1
Protocol deviation	-	1

Baseline characteristics

Reporting groups	
Reporting group title	Active
Reporting group description:	
Bilateral transmuscular quadratus lumborum block with 2 x 30 ml 0.375% ropivacain	
Reporting group title	Control
Reporting group description:	
Bilat. transmuscular quadratus lumborum block with 2 x 30 ml saline.	

Reporting group values	Active	Control	Total
Number of subjects	36	36	72
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	32.3	31.5	
standard deviation	± 5.7	± 4.9	-
Gender categorical			
Units: Subjects			
Female	36	36	72
Male	0	0	0

End points

End points reporting groups

Reporting group title	Active
Reporting group description:	
Bilateral transmuscular quadratus lumborum block with 2 x 30 ml 0.375% ropivacain	
Reporting group title	Control
Reporting group description:	
Bilat. transmuscular quadratus lumborum block with 2 x 30 ml saline.	

Primary: OME, oral morphine equivalents

End point title	OME, oral morphine equivalents
End point description:	
Morphine consumption was recorded from the PCA-pumps (5 mg morphine IV per bolus) and with any additional administration (oral or IV) during the first 24 hour period after block application.	
End point type	Primary
End point timeframe:	
24 hour opioid consumption	

End point values	Active	Control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	34	34		
Units: mg	65	94		

Statistical analyses

Statistical analysis title	T-test
Comparison groups	Active v Control
Number of subjects included in analysis	68
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.03
Method	t-test, 2-sided

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

Adverse events would be expected in the immediate time after administration of blocks (minutes), but possible adverse events were recorded in the first 48 hours.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	10.0

Reporting groups

Reporting group title	Any event related to TQL ropivacaine

Reporting group description: -

Serious adverse events	Any event related to TQL ropivacaine		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 70 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	Any event related to TQL ropivacaine		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 70 (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 a few registered non-serious adverse events recorded. Most of these (PONV) related to the administration of morphine (not study medicine) and a few other were mostly related to the spinal anaesthesia and the surgery. None of the recorded adverse events were considered related to the study medicine (ropivacaine or saline used in the TQL block).

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