



Clinical trial results:

Ultrasound-guided Transmuscular Quadratus Lumborum catheters for elective caesarean section.

A double blind, randomised, placebo controlled trial.

Summary

EudraCT number	2017-003625-15
Trial protocol	DK
Global end of trial date	08 April 2020

Results information

Result version number	v1 (current)
This version publication date	14 September 2022
First version publication date	14 September 2022

Trial information

Trial identification

Sponsor protocol code	Cath_TQL_caesarean_version1
-----------------------	-----------------------------

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03068260
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 Anaesth., Zealand university hospital, Roskilde, 45 30700120, jedn@regionsjaelland.dk
Scientific contact	Jens Børglum, Dept. of Anaesth., Zealand 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	08 April 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	08 April 2020
Global end of trial reached?	Yes
Global end of trial date	08 April 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The aim of this study is to investigate whether it is possible to prolong time to first opioid with the TQL block by inserting catheters bilaterally, providing continuous analgesia, in patients undergoing elective CS. Our hypothesis is that it will be possible to significantly extend time to first opioid with the blockade by 66.6%, increasing it from a mean of 5.6 hours to a mean of 10 hours, and that bilateral TQL catheters will significantly reduce the Numerical Rating Scale (NRS) pain score (0-10/10) compared to the placebo group.

Protection of trial subjects:

All participants were treated in accordance to departmental standard of care. The intervention was accepted with a minimum of or no discomfort at all due to the still pain relieving effect of the spinal anaesthesia used for the cesarean section. In addition, all participants were instructed in the use of an ekstra patient-controlled mode of pain relief via the patient-controlled analgesia pump with a morphine medication attached to the indwelling i.v.-line, which was on top of the standard treatment of paracetamol and NSAID's.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 May 2018
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: 32
Worldwide total number of subjects	32
EEA total number of subjects	32

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)	32
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

We obtained written informed consent from all patients prior to inclusion, and 32 subjects were enrolled at Zealand University Hospital, Denmark from September 4, 2018 to April 7, 2020

Pre-assignment

Screening details:

Overall, 131 patients were screened for eligibility from August 2018 to April 2020. Following informed consent, 32 participants were enrolled in the study and randomized. No important differences in patient characteristics was observed between the two study groups.

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, Carer

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo/saline group

Arm description:

Standard treatment of care + placebo, normal saline TQL re-injection and infusion through TQL-catheter.

Re-injection was performed 2 hours post-catheter placement and infusion commenced immediately afterwards.

Arm type	Placebo
Investigational medicinal product name	normal saline
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection/infusion
Routes of administration	Injection

Dosage and administration details:

2 (bilateral injections) x 30 mL saline 0,9% at T2 hours + continuous infusion via a Y-connector of saline 0,9% with a flow of 4 mL/hour per catheter.

Arm title	Active/ropivacaine TQL re-injection and infusion
------------------	--------------------------------------------------

Arm description:

Standard treatment of care + active, ropivacaine TQL re-injection and infusion through TQL-catheter.

Re-injection was performed 2 hours post-catheter placement and infusion commenced immediately afterwards.

Arm type	Active comparator
Investigational medicinal product name	ropivacaine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection/infusion
Routes of administration	Injection

Dosage and administration details:

2 (bilateral injections) x 30 mL ropivacaine 2 mg/ml at T2 hours (120 mg) + continuous infusion via a Y-connector of 2 mg/ml ropivacaine with a flow of 4 mL/hour per catheter (352 mg in 22 hours).

Number of subjects in period 1	Placebo/saline group	Active/ropivacaine TQL re-injection and infusion
Started	16	16
Completed	16	16

Baseline characteristics

Reporting groups

Reporting group title	Overall trial
Reporting group description: -	

Reporting group values	Overall trial	Total	
Number of subjects	32	32	
Age categorical			
Units: Subjects			
Adults (18-64 years)	32	32	
Gender categorical			
All trial participants in this study were female			
Units: Subjects			
Female	32	32	

End points

End points reporting groups

Reporting group title	Placebo/saline group
Reporting group description: Standard treatment of care + placebo, normal saline TQL re-injection and infusion through TQL-catheter. Re-injection was performed 2 hours post-catheter placement and infusion commenced immediately afterwards.	
Reporting group title	Active/ropivacaine TQL re-injection and infusion
Reporting group description: Standard treatment of care + active, ropivacaine TQL re-injection and infusion through TQL-catheter. Re-injection was performed 2 hours post-catheter placement and infusion commenced immediately afterwards.	

Primary: Time to first opioid consumption

End point title	Time to first opioid consumption
End point description:	
End point type	Primary
End point timeframe: first 24 hours post primary TQL injection and catheter placement	

End point values	Placebo/saline group	Active/ropivacaine TQL re-injection and infusion		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	12		
Units: minute				
median (inter-quartile range (Q1-Q3))	428 (245 to 552)	414 (283 to 597)		

Statistical analyses

Statistical analysis title	primary end point
Statistical analysis description: Mann-Whitney test	
Comparison groups	Placebo/saline group v Active/ropivacaine TQL re-injection and infusion

Number of subjects included in analysis	27
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.89
Method	Wilcoxon (Mann-Whitney)

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

From first intervention and until 24 hours after the last use of study medication.

Assessment type	Systematic
-----------------	------------

Dictionary used

Dictionary name	SUSAR, SAE, SE
-----------------	----------------

Dictionary version	1
--------------------	---

Reporting groups

Reporting group title	Both groups
-----------------------	-------------

Reporting group description:

Both groups

Serious adverse events	Both groups		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 32 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	Both groups		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 32 (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 recorded in the study period

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