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

Summary

EudraCT number	2017-004593-34
Trial protocol	DK
Global end of trial date	27 November 2019

Results information

Result version number	v1 (current)
This version publication date	24 February 2021
First version publication date	24 February 2021

Trial information

Trial identification

Sponsor protocol code	2017-070

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	ZUH, Roskilde
Sponsor organisation address	Sygehusvej 10, Roskilde, Denmark, 4000
Public contact	Jens Børglum, Dept. of Anesth. Zealand University Hospital Roskilde, +45 30700120, jedn@regionsjaelland.dk
Scientific contact	Jens Børglum, Dept. of Anesth. 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	01 May 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	27 November 2019
Global end of trial reached?	Yes
Global end of trial date	27 November 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Aim:
Our aim with this study is to investigate the efficacy of the Ultrasound-guided (USG) Transmuscular Quadratus Lumborum (TQL) block vs. Placebo in patients undergoing Total Laparoscopic Hysterectomy (TLH).
Our hypothesis is that the bilateral TQL block will significantly reduce the opioid consumption during the first 12 postoperative hours.

Protection of trial subjects:

Participants were closely monitores by study assistants and got at least the standard of care of the department

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 March 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: 70
Worldwide total number of subjects	70
EEA total number of subjects	70

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)	40

From 65 to 84 years	28
85 years and over	2

Subject disposition

Recruitment

Recruitment details:

70 subjects were enrolled at Zealand University Hospital, Denmark from September 28 2018 to November 8 2019.

Pre-assignment

Screening details:

140 subjects were assessed for elgibility. Most of those excluded was due to 'declined to participate'

Pre-assignment period milestones

Number of subjects started	70
Number of subjects completed	70

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, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	active

Arm description:

TQL block with active medication.

Arm type	Active comparator
Investigational medicinal product name	ropivacaine
Investigational medicinal product code	N01BB09
Other name	
Pharmaceutical forms	Injection
Routes of administration	Infiltration

Dosage and administration details:

Bilateral transmuscular quadratus lumborum block. 2 x 30 mL ropivacaine 0.375% (3.75 mg/mL with each block (bilateral)) = 225 mg in total.

Arm title	Control, NaCl

Arm description:

TQL block bilateral with in-active substance (NaCl) in the same volume of 30 mL at each side.

Arm type	Placebo
Investigational medicinal product name	Saline
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Infiltration

Dosage and administration details:

TQL blocks were administered with 30 ml of isotonic saline (NaCl) injected at each side

Number of subjects in period 1	active	Control, NaCl
Started	35	35
Completed	35	35

Baseline characteristics

Reporting groups	
Reporting group title	active
Reporting group description: TQL block with active medication.	
Reporting group title	Control, NaCl
Reporting group description: TQL block bilateral with in-active substance (NaCl) in the same volume of 30 mL at each side.	

Reporting group values	active	Control, NaCl	Total
Number of subjects	35	35	70
Age categorical Units: Subjects			
Adults (18-64 years)	21	19	40
From 65-84 years	13	15	28
85 years and over	1	1	2
Gender categorical Units: Subjects			
Female	35	35	70
Male	0	0	0

End points

End points reporting groups	
Reporting group title	active
Reporting group description:	
TQL block with active medication.	
Reporting group title	Control, NaCl
Reporting group description:	
TQL block bilateral with in-active substance (NaCl) in the same volume of 30 mL at each side.	

Primary: cumulated oral morphine equivalent consumption (mg)	
End point title	cumulated oral morphine equivalent consumption (mg)
End point description:	
Opioid usage from patient-controlled analgesia - pump and supplemental opioids administered by the nurses of the postoperative care or ward, All reported as cumulated oral morphine equivalents.	
End point type	Primary
End point timeframe:	
The first 12 postoperative hours	

End point values	active	Control, NaCl		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	35	34		
Units: miligram	58	64		

Attachments (see zip file)	Results table from TQL TLH in RAPM/Table 2 TQL TLH RAPM.

Statistical analyses

Statistical analysis title	Student’s unpaired t-test
Comparison groups	active v Control, NaCl
Number of subjects included in analysis	69
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.05
Method	t-test, 2-sided

Secondary: Oral morphine equivalents in mg, 0–6 hours	
End point title	Oral morphine equivalents in mg, 0–6 hours
End point description:	

End point type	Secondary
End point timeframe: 0-6 hors postoperatively	

End point values	active	Control, NaCl		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	35	34		
Units: mg	56	59		

Statistical analyses

Statistical analysis title	Student’s unpaired t-test.
Comparison groups	active v Control, NaCl
Number of subjects included in analysis	69
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.05
Method	t-test, 2-sided

Secondary: Oral morphine equivalents 6-12

End point title	Oral morphine equivalents 6-12
End point description:	

End point type	Secondary
End point timeframe: 6-12 hours postoperatively	

End point values	active	Control, NaCl		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	35	34		
Units: mg	0	0		

Statistical analyses

Statistical analysis title	Mann-Whitney test
Comparison groups	active v Control, NaCl

Number of subjects included in analysis	69
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.05
Method	Wilcoxon (Mann-Whitney)

Secondary: Oral morphine equivalents 12–18 hours

End point title	Oral morphine equivalents 12–18 hours

End point description:

End point type	Secondary

End point timeframe:

12-18 hours postoperatively

End point values	active	Control, NaCl		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	35	34		
Units: mg	0	0		

Statistical analyses

Statistical analysis title	Mann-Whitney test
Comparison groups	active v Control, NaCl
Number of subjects included in analysis	69
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.05
Method	Wilcoxon (Mann-Whitney)

Secondary: Oral morphine equivalents 18-24

End point title	Oral morphine equivalents 18-24

End point description:

End point type	Secondary

End point timeframe:

12-18 hours postoperatively

End point values	active	Control, NaCl		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	35	34		
Units: mg	0	0		

Statistical analyses

Statistical analysis title	Mann-Whitney test
Comparison groups	active v Control, NaCl
Number of subjects included in analysis	69
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.05
Method	Wilcoxon (Mann-Whitney)

Secondary: Oral morphine equivalents 0-24 hours

End point title	Oral morphine equivalents 0-24 hours

End point description:

End point type	Secondary

End point timeframe:

0-24 hours postoperatively

End point values	active	Control, NaCl		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	35	34		
Units: mg	63	69		

Statistical analyses

Statistical analysis title	Student’s unpaired t-test
Comparison groups	active v Control, NaCl
Number of subjects included in analysis	69
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.05
Method	t-test, 2-sided

Secondary: median NRS at rest 0-6

End point title	median NRS at rest 0-6

End point description:

End point type	Secondary

End point timeframe:

0-6 hours postoperatively

End point values	active	Control, NaCl		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	35	34		
Units: NRS units	4	4		

Statistical analyses

Statistical analysis title	Mann-Whitney test
Comparison groups	active v Control, NaCl
Number of subjects included in analysis	69
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.05
Method	Wilcoxon (Mann-Whitney)

Secondary: median NRS at rest 6-12 hours

End point title	median NRS at rest 6-12 hours

End point description:

End point type	Secondary

End point timeframe:

6-12 hours postoperatively

End point values	active	Control, NaCl		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	35	34		
Units: NRS units	1	1		

Statistical analyses

Statistical analysis title	Mann-Whitney test
Comparison groups	active v Control, NaCl
Number of subjects included in analysis	69
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.05
Method	Wilcoxon (Mann-Whitney)

Secondary: median NRS at rest 12-18 hours

End point title	median NRS at rest 12-18 hours

End point description:

End point type	Secondary

End point timeframe:

12-18 hours postoperatively

End point values	active	Control, NaCl		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	35	34		
Units: NRS units	1	1		

Statistical analyses

Statistical analysis title	Mann-Whitney test
Comparison groups	active v Control, NaCl
Number of subjects included in analysis	69
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.05
Method	Wilcoxon (Mann-Whitney)

Secondary: median NRS at rest 18-24 hours

End point title	median NRS at rest 18-24 hours

End point description:

End point type	Secondary

End point timeframe:

18-24 hours postoperatively

End point values	active	Control, NaCl		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	35	34		
Units: NRS units	0	1		

Statistical analyses

Statistical analysis title	Mann-Whitney test
Comparison groups	active v Control, NaCl
Number of subjects included in analysis	69
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.05
Method	Wilcoxon (Mann-Whitney)

Secondary: Median NRS score during block performance

End point title	Median NRS score during block performance

End point description:

End point type	Secondary

End point timeframe:

regsitered immediately after block performance

End point values	active	Control, NaCl		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	35	35		
Units: NRS units	2	2		

Statistical analyses

Statistical analysis title	Mann-Whitney test
Comparison groups	active v Control, NaCl

Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.05
Method	Wilcoxon (Mann-Whitney)

Secondary: Mean time to first sitting up in bed

End point title	Mean time to first sitting up in bed

End point description:

End point type	Secondary

End point timeframe:

During followup of up to 24 hours.

End point values	active	Control, NaCl		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	35	34		
Units: minutes	217	254		

Statistical analyses

Statistical analysis title	Student’s unpaired t-test
Comparison groups	active v Control, NaCl
Number of subjects included in analysis	69
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.05
Method	t-test, 2-sided

Secondary: Time to first opioid in minutes

End point title	Time to first opioid in minutes

End point description:

End point type	Secondary

End point timeframe:

Time during follow-up of up to 24 hours.

End point values	active	Control, NaCl		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	27	28		
Units: minutes	12	15		

Statistical analyses

Statistical analysis title	Mann-Whitney test
Comparison groups	active v Control, NaCl
Number of subjects included in analysis	55
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.05
Method	Wilcoxon (Mann-Whitney)

Secondary: Time to first ambulation

End point title	Time to first ambulation

End point description:

End point type	Secondary

End point timeframe:

Time during follow-up of up to 24 hours.

End point values	active	Control, NaCl		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	35	34		
Units: minutes	283	298		

Statistical analyses

Statistical analysis title	Student’s unpaired t-test
Comparison groups	active v Control, NaCl
Number of subjects included in analysis	69
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.05
Method	t-test, 2-sided

Secondary: PONV during follow-up

End point title	PONV during follow-up

End point description:

End point type	Secondary

End point timeframe:

Time during follow-up of up to 24 hours.

End point values	active	Control, NaCl		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	35	34		
Units: numbers	16	13		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Participants were closely monitored during the study period of up til 24 hours (shorter if released earlier from dep. of gynaecology).
After admission ended participants were encouraged to contact study investigator/sponsor if adverse reactions occured.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	2.1

Reporting groups

Reporting group title	active

Reporting group description:

TQL block with active medication.

Reporting group title	Control, NaCl

Reporting group description:

TQL block bilateral with in-active substance (NaCl) in the same volume of 30 mL at each side.

Serious adverse events	active	Control, NaCl	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 35 (0.00%)	0 / 35 (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	active	Control, NaCl	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 35 (22.86%)	9 / 35 (25.71%)	
Nervous system disorders			
Nausea	Additional description: The dominant adverse reaction was PONV (postoperative nausea and vomiting) with only a few productive vomiting but a substantial amount of participants experiencing nausea from the escape medication (i.v. morphine, tuypically)		
subjects affected / exposed	8 / 35 (22.86%)	9 / 35 (25.71%)	
occurrences (all)	8	9	

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