Clinical trial results:
Optimal postoperative pain management by ultrasoundguided abdominal wall nerve blockade for laparoscopic surgery for acute appendicitis - a randomised controlled trial.

Summary

EudraCT number	2013-001400-11
Trial protocol	DK
Global end of trial date	14 December 2013

Results information

Result version number	v1 (current)
This version publication date	20 November 2021
First version publication date	20 November 2021

Trial information

Trial identification

Sponsor protocol code	BBH-BDTAP-APP

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01825863
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Department of Anaesthesiology and Intensive Care
Sponsor organisation address	Bispebjerg Bakke 23, Copenhagen, Denmark, 2400
Public contact	Department of anesthesiology Z, Bispebjerg Hospital, 45 35 31 27 83, z-afd.bispebjerghospital@regionh.dk
Scientific contact	Department of anesthesiology Z, Bispebjerg Hospital, 45 35 31 27 83, z-afd.bispebjerghospital@regionh.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	05 January 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	14 December 2013
Global end of trial reached?	Yes
Global end of trial date	14 December 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To explore weather the use of the BD-TAP abdominal wall blockade for patients undergoing laparoscopic surgery due to acute appendicits can anesthetize the patients and therefore reduce the patient's postoperative pain and thus reduce their postoperative morphine consumption.
The main objective is pain score in motion, from lying flat in bed to sitting up, assessed 0-12 hours postoperatively using the nummerical rating scale (NRS) 0-10.

Protection of trial subjects:

All patients had their BD-TAP block administered while under general anaesthesia thus minimizing discomfort and pain. A PCA pump was fitted at the PACU to ensure sufficient postoperative pain management.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 May 2013
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: 56
Worldwide total number of subjects	56
EEA total number of subjects	56

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)	56
From 65 to 84 years	0

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This was a single center study with all patients being recruited at Bispebjerg Hospital, Denmark.
All patients admitted with acute appendicitis schduled for a laparoscopic appendectomy were screened.

Pre-assignment

Screening details:

84 patients were screened, 56 patients were included, 15 were excluded due to not meeting inclusion criteria , 7 declined to participate, 4 were not included due to logistical reasons , 2 had their surgery cancelled

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, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Active

Arm description:

All patients in this arm received a bilateral dual TAP-blok with 60 mL 0.375% ropivacaine

Arm type	Active comparator
Investigational medicinal product name	Ropivacaine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection
Routes of administration	Perineural use

Dosage and administration details:

60 mL of 0.375% ropivacaine was administered as an ultrasound-guided nerve block

Arm title	Placebo

Arm description:

All patients in this arm received a bilateral dual TAP block wit 60 mL isotonic saline

Arm type	Placebo
Investigational medicinal product name	Natrium Chloride (isotonic)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection
Routes of administration	Perineural use

Dosage and administration details:

Each participant received a BD-TAP block with 60 mL isotonic saline

Number of subjects in period 1	Active	Placebo
Started	28	28
Completed	27	25
Not completed	1	3
Cancelled surgery	-	1
Equipment failure	-	1
Protocol deviation	1	1

Baseline characteristics

Reporting groups	
Reporting group title	Active
Reporting group description:	
All patients in this arm received a bilateral dual TAP-blok with 60 mL 0.375% ropivacaine	
Reporting group title	Placebo
Reporting group description:	
All patients in this arm received a bilateral dual TAP block wit 60 mL isotonic saline	

Reporting group values	Active	Placebo	Total
Number of subjects	28	28	56
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	32.1	29.1	
standard deviation	± 14.3	± 10.7	-
Gender categorical Units: Subjects			
Female	13	16	29
Male	15	12	27
American Society of Anaesthesiology - group Units: Subjects			
One	23	21	44
Two	5	6	11
Three	0	1	1
Weight Units: kilogram(s)			
arithmetic mean	77.5	73.1	
standard deviation	± 14.8	± 13.8	-

End points

End points reporting groups

Reporting group title	Active
Reporting group description:	
All patients in this arm received a bilateral dual TAP-blok with 60 mL 0.375% ropivacaine	
Reporting group title	Placebo
Reporting group description:	
All patients in this arm received a bilateral dual TAP block wit 60 mL isotonic saline	

Primary: Pain at mobilisation 0-12 hours

End point title	Pain at mobilisation 0-12 hours
End point description:	
End point type	Primary
End point timeframe:	
0-12 hours after surgery	

End point values	Active	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	27	25		
Units: Area under the curve				
median (inter-quartile range (Q1-Q3))	34 (19 to 46)	50 (30 to 59)		

Statistical analyses

Statistical analysis title	Mann-Whitney test
Comparison groups	Active v Placebo
Number of subjects included in analysis	52
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.009
Method	Wilcoxon (Mann-Whitney)

Secondary: Pain 0-12 hours (at rest)

End point title	Pain 0-12 hours (at rest)
End point description:	
End point type	Secondary

End point timeframe:
0-12 hours post surgery

End point values	Active	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	27	25		
Units: Nummerical rating scale				
median (inter-quartile range (Q1-Q3))	25 (10 to 33)	31 (24 to 43)		

Statistical analyses

No statistical analyses for this end point

Secondary: Morphine consumption

End point title	Morphine consumption

End point description:

End point type	Secondary

End point timeframe:
Total opioid consumption 0-12 hours post surgery

End point values	Active	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	27	25		
Units: Miligrams				
median (inter-quartile range (Q1-Q3))	10 (0 to 18)	20 (5 to 30)		

Statistical analyses

No statistical analyses for this end point

Secondary: Nausea

End point title	Nausea

End point description:

End point type	Secondary

End point timeframe:
Any patients with nausea 0-12 hours post surgery

End point values	Active	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	27	25		
Units: Subjects	15	14		

Statistical analyses

No statistical analyses for this end point

Secondary: Postoperative antiemetics

End point title	Postoperative antiemetics

End point description:

End point type	Secondary

End point timeframe:

Number of patients needing antiemetics 0-12 hours post surgery

End point values	Active	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	27	25		
Units: subjects	10	11		

Statistical analyses

No statistical analyses for this end point

Secondary: Time at the PACU unit

End point title	Time at the PACU unit

End point description:

End point type	Secondary

End point timeframe:

Number of minutes spend at the Post Anaesthesia Care Unit

End point values	Active	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	27	25		
Units: Minutes				
median (inter-quartile range (Q1-Q3))	85 (63 to 100)	80 (70 to 115)		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to mobilisation

End point title	Time to mobilisation

End point description:

End point type	Secondary

End point timeframe:

Time to mobilisation post surgery (hours)

End point values	Active	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	27	25		
Units: Hours				
median (inter-quartile range (Q1-Q3))	5.5 (3.1 to 8.3)	6.7 (4.5 to 12.9)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

The inclusion period was less than a year and so the annual adverse event report was submitted with the end of trial registration

Adverse event reporting additional description:

3 patients were readmitted during the first 30 days post surgery. Non of these adverse events were believed to be associated with the trial mediciation

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	10.0

Reporting groups

Reporting group title	Active/ropivacaine

Reporting group description:

One patient was readmitted with flu-like symptoms believed not to be associated with the treatment

Reporting group title	Placebo/isotonic saline

Reporting group description:

One patient was readmitted with abdominal pain and one with and incisional abscess. Both incidents believed not to be associated with the trial medication

Serious adverse events	Active/ropivacaine	Placebo/isotonic saline	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (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: 2 %

Non-serious adverse events	Active/ropivacaine	Placebo/isotonic saline	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)	2 / 2 (100.00%)	
Surgical and medical procedures			
Complications after appendectomy			
subjects affected / exposed	1 / 1 (100.00%)	2 / 2 (100.00%)	
occurrences (all)	1	2	

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/26464041