



Clinical trial results:

Comparison of the analgesic effect of an adductor canal block using a new suture-method catheter vs a standard perineural catheter vs a single bolus:

A randomized, blinded, controlled study

Summary

EudraCT number	2016-005069-30
Trial protocol	DK
Global end of trial date	20 April 2018

Results information

Result version number	v1 (current)
This version publication date	14 November 2019
First version publication date	14 November 2019

Trial information

Trial identification

Sponsor protocol code	UG1_2016
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03142789
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Gentofte Hospital
Sponsor organisation address	Hospitalsvej 1, Copenhagen, Denmark,
Public contact	Department of anesthesia, Gentofte Hospital, +45 38673867, jens.ulrik.grevstad@regionh.dk
Scientific contact	Department of anesthesia, Gentofte Hospital, +45 38673867, jens.ulrik.grevstad@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	20 May 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	20 April 2018
Global end of trial reached?	Yes
Global end of trial date	20 April 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The aim of the study is to compare the clinical effects of three different administration forms for an ACB: repeated intermittent boluses through a Certa catheter (CC) versus repeated boluses through a standard catheter (through the needle) (SC) versus a single bolus (SB). Our dual hypothesis is that repeated boluses through a catheter (either Certa or standard catheter) reduces opioid consumption (primary outcome), as well as reduces pain scores, enhances ambulation and muscle strength compared with a single bolus, and that the Certa catheter is superior to a standard catheter.

Protection of trial subjects:

All patients had a PCA with opioids

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: 153
Worldwide total number of subjects	153
EEA total number of subjects	153

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)	34
From 65 to 84 years	113
85 years and over	6

Subject disposition

Recruitment

Recruitment details:

Patients were recruited at Gentofte Hospital, Denmark, from May 2017 to May 2018

Pre-assignment

Screening details:

402 patients were assessed for eligibility, and 249 excluded

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind ^[1]
Roles blinded	Subject, Monitor, Data analyst, Carer, Assessor

Blinding implementation details:

All patients received the allocated intervention in the PACU immediately after surgery, before spinal anaesthesia had worn off. Opaque sterile drapings covered the view of patients during the

procedure. After block procedure, the mid-thigh was covered with opaque dressings and the pump was set to a lock-level that avoided visible pump settings. Thus, all investigators, clinical staff, and patients were blinded to group allocation except for the investigator who performed the intervention.

Arms

Are arms mutually exclusive?	Yes
Arm title	Certa catheter

Arm description:

Patients received an ACB after surgery with an initial bolus of 20 ml 0.75% ropivacaine, followed by 20 ml of 0.2% ropivacaine every 8 hours in the suture-method catheter until 12:00 on postoperative day (POD) 2

Arm type	Experimental
Investigational medicinal product name	Ropivacaine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Perineural use

Dosage and administration details:

20ml of 0,2% + bolus 20 ml of 0,2% every 8 hours until 12:00 on POD2

Arm title	Standard catheter
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Arm description:

patients received an ACB after surgery with an initial bolus of 20 ml 0.75% ropivacaine, followed by 20 ml of 0.2% ropivacaine every 8 hours in the standard catheter until 12:00 on postoperative day (POD) 2

Arm type	Active comparator
Investigational medicinal product name	Ropivacaine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Perineural use

Dosage and administration details:

20ml of 0,2% + bolus 20 ml of 0,2% every 8 hours until 12:00 on POD2

Arm title	Single bolus
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Arm description:

patients received an ACB after surgery with an initial bolus of 20 ml 0.75% ropivacaine, followed by 0.1 ml of 0.2% ropivacaine every 8 hours in the sham catheter until 12:00 on postoperative day (POD) 2

Arm type	Active comparator
Investigational medicinal product name	Ropivacaine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Perineural use

Dosage and administration details:

20ml of 0,2% + sham bolus 0.1 ml of 0,2% every 8 hours until 12:00 on POD2

Notes:

[1] - The roles blinded appear to be inconsistent with a double blind trial.

Justification: We have described who is blinded and believe the terms "single" and "double" blinded are obsolete

Number of subjects in period 1	Certa catheter	Standard catheter	Single bolus
Started	51	51	51
Completed	51	51	51

Baseline characteristics

Reporting groups

Reporting group title

Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	153	153	
Age categorical			
Units: Subjects			
Adults (18-64 years)	34	34	
From 65-84 years	113	113	
85 years and over	6	6	
Age continuous			
Units: years			
arithmetic mean	70		
full range (min-max)	49 to 83	-	
Gender categorical			
Units: Subjects			
Female	98	98	
Male	55	55	

End points

End points reporting groups

Reporting group title	Certa catheter
Reporting group description: Patients received an ACB after surgery with an initial bolus of 20 ml 0.75% ropivacaine, followed by 20 ml of 0.2% ropivacaine every 8 hours in the suture-method catheter until 12:00 on postoperative day (POD) 2	
Reporting group title	Standard catheter
Reporting group description: patients received an ACB after surgery with an initial bolus of 20 ml 0.75% ropivacaine, followed by 20 ml of 0.2% ropivacaine every 8 hours in the standard catheter until 12:00 on postoperative day (POD) 2	
Reporting group title	Single bolus
Reporting group description: patients received an ACB after surgery with an initial bolus of 20 ml 0.75% ropivacaine, followed by 0.1 ml of 0.2% ropivacaine every 8 hours in the sham catheter until 12:00 on postoperative day (POD) 2	

Primary: Total opioid consumption

End point title	Total opioid consumption
End point description: Total opioid consumption in intravenous morphine equivalents in mg	
End point type	Primary
End point timeframe: From arrival at postoperative care unit until 12:00 on post operative day 2	

End point values	Certa catheter	Standard catheter	Single bolus	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	51	49	49	
Units: mg				
median (full range (min-max))	24 (0 to 148)	38 (0 to 123)	37 (0 to 158)	

Statistical analyses

Statistical analysis title	overall
Statistical analysis description: Statistical analysis was performed using SPSS 22;. None of the variables, except 6-minute walk tests, was normally distributed, based on skewness, kurtosis, visual inspection of their histograms, Q-Q plots, box plots and Shapiro-Wilk tests. Consequently, all variables were analysed using nonparametric tests.	
Comparison groups	Certa catheter v Standard catheter v Single bolus

Number of subjects included in analysis	149
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	Kruskal-wallis
Parameter estimate	Median difference (net)

Secondary: Quadriceps strength % of baseline on POD1

End point title	Quadriceps strength % of baseline on POD1
End point description: Muscle strength was assessed as maximum voluntary isometric contraction (MVIC) of the quadriceps femoris muscle using a handheld dynamometer (Lafayette Instrument, Lafayette, IN) before surgery and 12:00 on POD 1	
End point type	Secondary
End point timeframe: 12:00 on postoperative day 1	

End point values	Certa catheter	Standard catheter	Single bolus	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	51	49	49	
Units: Percent				
median (inter-quartile range (Q1-Q3))	35 (27 to 50)	46 (25 to 62)	37 (21 to 69)	

Statistical analyses

No statistical analyses for this end point

Secondary: Quadriceps strength % of baseline on POD2

End point title	Quadriceps strength % of baseline on POD2
End point description: Muscle strength was assessed as maximum voluntary isometric contraction (MVIC) of the quadriceps femoris muscle using a handheld dynamometer (Lafayette Instrument, Lafayette, IN) before surgery and 12:00 on POD 2	
End point type	Secondary
End point timeframe: 12:00 on POD2	

End point values	Certa catheter	Standard catheter	Single bolus	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	51	49	49	
Units: Percent				
median (inter-quartile range (Q1-Q3))	31 (21 to 46)	27 (22 to 59)	18 (0 to 32)	

Statistical analyses

No statistical analyses for this end point

Secondary: 6 minute walk test - POD1

End point title	6 minute walk test - POD1
End point description:	
End point type	Secondary
End point timeframe:	
12:00 POD 1	

End point values	Certa catheter	Standard catheter	Single bolus	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	51	49	49	
Units: meter				
median (inter-quartile range (Q1-Q3))	200 (85 to 264)	184 (113 to 260)	160 (76 to 240)	

Statistical analyses

No statistical analyses for this end point

Secondary: 6 minute walk test - POD2

End point title	6 minute walk test - POD2
End point description:	
End point type	Secondary
End point timeframe:	
POD2	

End point values	Certa catheter	Standard catheter	Single bolus	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	51	49	49	
Units: meter				
median (inter-quartile range (Q1-Q3))	215 (104 to 265)	200 (133 to 266)	131 (46 to 207)	

Statistical analyses

No statistical analyses for this end point

Secondary: TUG test POD1

End point title	TUG test POD1
End point description: Timed Up and Go test	
End point type	Secondary
End point timeframe: 12:00 POD1	

End point values	Certa catheter	Standard catheter	Single bolus	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	51	49	49	
Units: second				
median (inter-quartile range (Q1-Q3))	24 (19 to 34)	29 (20 to 41)	27 (19 to 46)	

Statistical analyses

No statistical analyses for this end point

Secondary: TUG POD2

End point title	TUG POD2
End point description: Timed Up and Go test	
End point type	Secondary
End point timeframe: 12:00 POD2	

End point values	Certa catheter	Standard catheter	Single bolus	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	51	49	49	
Units: second				
median (inter-quartile range (Q1-Q3))	26 (20 to 36)	27 (20 to 37)	26 (24 to 64)	

Statistical analyses

No statistical analyses for this end point

Secondary: Worst pain during TUG on POD1

End point title	Worst pain during TUG on POD1
End point description:	
End point type	Secondary
End point timeframe:	
12:00 POD1	

End point values	Certa catheter	Standard catheter	Single bolus	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	51	49	49	
Units: mm on VAS				
median (inter-quartile range (Q1-Q3))	26 (11 to 51)	29 (15 to 49)	36 (18 to 62)	

Statistical analyses

No statistical analyses for this end point

Secondary: Worst pain during TUG on POD2

End point title	Worst pain during TUG on POD2
End point description:	
End point type	Secondary
End point timeframe:	
12:00 POD2	

End point values	Certa catheter	Standard catheter	Single bolus	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	51	49	49	
Units: mm on a VAS				
median (inter-quartile range (Q1-Q3))	21 (13 to 45)	21 (7 to 35)	46 (24 to 87)	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

From intervention until 12:00 on postoperative day 2

Assessment type	Non-systematic
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Dictionary used

Dictionary name	none
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Dictionary version	1
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Reporting groups

Reporting group title	overall
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Reporting group description: -

Serious adverse events	overall		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 153 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	overall		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 153 (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: None were recorded

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