Clinical trial results:
The effect of popliteal plexus block on pain after total knee replacement.

Summary

EudraCT number	2017-001644-35
Trial protocol	DK
Global end of trial date	20 February 2018

Results information

Result version number	v1 (current)
This version publication date	24 June 2020
First version publication date	24 June 2020
Summary attachment (see zip file)	Article (Runge_et_al-2018-Acta_Anaesthesiologica_Scandinavica.pdf)

Trial information

Trial identification

Sponsor protocol code	CR_TFB_2017

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03198403
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Aarhus University Hospital
Sponsor organisation address	Nørrebrogade 44, Aarhus, Denmark, 8000
Public contact	Centre of Elective Surgery, Silkeborg Regional Hospital, 0045 25883172,
Scientific contact	Centre of Elective Surgery, Silkeborg Regional Hospital, 0045 25883172, charlotte.runge@aarhus.rm.dk
Sponsor organisation name	Aarhus University
Sponsor organisation address	Nørrebrogade 44, Aarhus, Denmark, 8000
Public contact	Silkeborg regional hospital, Aarhus university hospital, 0045 25883172, charlotte.runge@aarhus.rm.dk
Scientific contact	Silkeborg regional hospital, Anesthesia depart., Aarhus university hospital, 0045 51542997, tfb@dadlnet.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 February 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	20 February 2018
Global end of trial reached?	Yes
Global end of trial date	20 February 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The aim of this trial is to evaluate the effect of popliteal plexus block (PPB) on pain after total knee replacement (TKR)

Protection of trial subjects:

The trial was monitored by the Good Clinical Practice (GCP) Unit at Aalborg and Aarhus University Hospitals. Written informed consent was obtained from all subjects.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 May 2017
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Denmark: 10
Worldwide total number of subjects	10
EEA total number of subjects	10

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)	2
From 65 to 84 years	8

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subjects were recruited at Silkeborg Regional Hospital, Denmark, from August to September 2017.

Pre-assignment

Screening details:

Eligibility criteria for the study included patients older than 18 years and American Society of Anaesthesiologists (ASA) score 13 who were scheduled for cemented, unilateral, primary TKA with spinal anaesthesia. The exclusion criteria were inability to cooperate, nonDanish speakers, pregnancy, diabetes, reduced sensation on the lower limb, daily

Period 1

Period 1 title	overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	active popliteal plexus block

Arm description:

patients received an active PPB, if NRS exceed 3

Arm type	Active comparator
Investigational medicinal product name	bupivacaine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for concentrate for solution for infusion
Routes of administration	Perineural use

Dosage and administration details:

10 mL of bupivacaine 5 mg/ml

Number of subjects in period 1	active popliteal plexus block
Started	10
Completed	10

Baseline characteristics

Reporting groups

Reporting group title	overall trial

Reporting group description: -

Reporting group values	overall trial	Total	
Number of subjects	10	10	
Age categorical			
Population are patients from 50 years and over.			
Units: Subjects			
Adults (18-64 years)	2	2	
From 65-84 years	8	8	
Age continuous			
Units: years			
median	70		
full range (min-max)	65 to 80	-	
Gender categorical			
Units: Subjects			
Female	4	4	
Male	6	6	

Subject analysis sets

Subject analysis set title	statistical analysis
Subject analysis set type	Full analysis

Subject analysis set description:

Statistical analysis was conducted with STATA 14 (Stata Corp, College Station, TX, USA). Continuous variables with normal distribution were presented as mean (standard deviation and confidence interval). Normality of distribution was tested with histograms and QQ-plots. Nonparametric distributions were presented as median (IQR, interquartile range). Paired comparison of non-Gaussian continuous variables (isometric muscle strength) was carried out with the Wilcoxon signed rank test.

Reporting group values	statistical analysis		
Number of subjects	10		
Age categorical			
Population are patients from 50 years and over.			
Units: Subjects			
Adults (18-64 years)	5		
From 65-84 years	12		
Age continuous			
Units: years			
median	70		
full range (min-max)	50 to 85		

Gender categorical Units: Subjects			
Female Male			

End points

End points reporting groups

Reporting group title	active popliteal plexus block

Reporting group description:

patients received an active PPB, if NRS exceed 3

Subject analysis set title	statistical analysis
Subject analysis set type	Full analysis

Subject analysis set description:

Statistical analysis was conducted with STATA 14 (Stata Corp, College Station, TX, USA). Continuous variables with normal distribution were presented as mean (standard deviation and confidence interval). Normality of distribution was tested with histograms and QQ-plots. Nonparametric distributions were presented as median (IQR, interquartile range). Paired comparison of non-Gaussian continuous variables (isometric muscle strength) was carried out with the Wilcoxon signed rank test.

Primary: pain reduction

End point title	pain reduction[1]

End point description:

If a subject reported a pain score of NRS >3, a PPB was carried out. Prior to the PPB, the location of pain was registered as pain in the anterior, the posterior, the medial, or the lateral aspect of the knee, deep knee pain, pain in the thigh or diffuse pain. The end of injection of the PPB was defined as popliteal plexus block time 0 (PPB t0) .
The pain score (NRS 0-10) and the cutaneous sensation (0-2) on the lateral side of the operated leg were assessed every 5 minutes after PPB t0 until NRS ≤3 or a maximum of 60 minutes after PPB t0 .

End point type	Primary

End point timeframe:

The primary outcome was the proportion of subjects reporting pain above NRS 3 within the observation period, who had a reduction in pain score to NRS ≤3 within 1 hour after PPB.

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The study was a feasibility study. Counting the number of patients having significant pain and apply percentage.

End point values	statistical analysis			
Subject group type	Subject analysis set			
Number of subjects analysed	17			
Units: subjects	10			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
No adverse events were observed.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	1

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

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: No adverse events were observed in the study

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