Clinical trial results:
The effect of protracted saphenous nerve and obturator nerve blockade versus saphenous nerve blockade versus local infiltration analgesia in opioid consumption, pain, blockade duration of action and mobilization after total knee arthroplasty.

Summary

EudraCT number	2013-005010-36
Trial protocol	DK
Global end of trial date	29 December 2014

Results information

Result version number	v1 (current)
This version publication date	23 January 2021
First version publication date	23 January 2021

Trial information

Trial identification

Sponsor protocol code	CR-TFB-2013/502

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02067078
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Aarhus University
Sponsor organisation address	Nørrebrogade 44, Aarhus, Denmark, 8000
Public contact	Centre of elective surgery, Hospital of Silkeborg, 0045 25883172, charlotte.runge@aarhus.rm.dk
Scientific contact	Centre of elective surgery, Hospital of Silkeborg, 0045 25883172, charlotte.runge@aarhus.rm.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	29 December 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	29 December 2014
Global end of trial reached?	Yes
Global end of trial date	29 December 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The aim is to investigate the effect of combined saphenous nerve and obturator nerve blockade with a mixture of local analgesics; bupivacain, adrenalin, clonidine and dexamethasone (protacted mixture), compared with saphenous nerve blockade with protracted mixture, compared with local infiltration analgesia in the tissue around the knee joint on opioid consumption after total knee arthroplasty.

Protection of trial subjects:

The subjects are registered by an trial number

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	18 February 2014
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: 75
Worldwide total number of subjects	75
EEA total number of subjects	75

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)	25
From 65 to 84 years	50
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Sceduled for primary total knee alloplasty in spinal anesthesia

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	Investigator, Monitor, Assessor, Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	Saphenous and obturator nerve group

Arm description:

Received active bupivacaine+ epinephrine+dexamethasone in the blockades

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

Dosage and administration details:

50 mg

Investigational medicinal product name	dexamethasone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for injection
Routes of administration	Perineural use

Dosage and administration details:

2 mg

Arm title	Saphenous block

Arm description:

Received saphneous blockade

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

Dosage and administration details:

50 mg

Investigational medicinal product name	dexamethasone
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:

2 mg

Arm title	Local infiltration analgesia

Arm description:

Received intraoperative local infiltration analgesia

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 1	Saphenous and obturator nerve group	Saphenous block	Local infiltration analgesia
Started	25	25	25
Completed	25	25	25

Baseline characteristics

End points

End points reporting groups	
Reporting group title	Saphenous and obturator nerve group
Reporting group description: Received active bupivacaine+ epinephrine+dexamethasone in the blockades	
Reporting group title	Saphenous block
Reporting group description: Received saphneous blockade	
Reporting group title	Local infiltration analgesia
Reporting group description: Received intraoperative local infiltration analgesia	

Primary: total opioid consumption during first 24 hours	
End point title	total opioid consumption during first 24 hours
End point description:	
End point type	Primary
End point timeframe: end of surgery to 24 hours after surgery	

End point values	Saphenous and obturator nerve group	Saphenous block	Local infiltration analgesia	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	25	25	25	
Units: milligram(s)/24 hours				
arithmetic mean (inter-quartile range (Q1-Q3))	2 (0 to 15)	20 (10 to 26)	17 (10 to 36)	

Statistical analyses

Statistical analysis title	nonparametric data
Statistical analysis description: The three groups were compared with Kruskal-Wallis test. If the P value was inferior to 0.05 the groups were compared 1:1 using the Mann-Whitney U test	
Comparison groups	Saphenous and obturator nerve group v Saphenous block v Local infiltration analgesia
Number of subjects included in analysis	75
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	Kruskal-wallis

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

0-14 days

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	1

Reporting groups

Reporting group title	studygroup

Reporting group description: -

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: All serious adverse events have been reported. No non-serious adverse events have registered.

Serious adverse events	studygroup		
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 75 (9.33%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events	1		
Cardiac disorders			
Sudden death			
subjects affected / exposed	1 / 75 (1.33%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 1		
Blood and lymphatic system disorders			
anemia			
subjects affected / exposed	2 / 75 (2.67%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Embolic pneumonia			
subjects affected / exposed	1 / 75 (1.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
hemorrhage			

subjects affected / exposed	1 / 75 (1.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
exacerbation in COLD			
subjects affected / exposed	1 / 75 (1.33%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Sepsis			
subjects affected / exposed	1 / 75 (1.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	studygroup		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 75 (0.00%)		

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