Clinical trial results:
"AnAnkle Trial": Peripheral nerve block vs. spinal anaesthesia for ankle fracture surgery – implications on pain profile and quality of recovery

Summary

EudraCT number	2015-001108-76
Trial protocol	DK
Global end of trial date	31 May 2017

Results information

Result version number	v1 (current)
This version publication date	25 June 2022
First version publication date	25 June 2022

Trial information

Trial identification

Sponsor protocol code	2015-735

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Herlev Hospital
Sponsor organisation address	Borgmester Ib Juuls Vej 1, Herlev, Denmark, 2730
Public contact	Department of Anaesthesiology I65N9, Herlev Hospital, rune.sort.03@regionh.dk
Scientific contact	Department of Anaesthesiology I65N9, Herlev Hospital, rune.sort.03@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	31 May 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 May 2017
Global end of trial reached?	Yes
Global end of trial date	31 May 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To study difference in combined short term postoperative pain and opioid use following peripheral nerve block (PNB) anaesthesia versus spinal anaesthesia (SA) for ankle fracture surgery.

Protection of trial subjects:

The interventions (peripheral nerve block anaesthesia versus spinal anaesthesia) were already part of standard clinical practice and performed with attention to minimising any pain, distress or discomfort, i.e. by providing thorough information, local anaesthesia and on-demand light sedation.

Background therapy:

Both arms received peroperative light sedation on demand and a postoperative pain treatment regimen of paracetamol 1 g every 6 hours, ibuprofene 400 mg every 8 hours and PCA on-demand i.v. morphine 2,5 mg pr. dose with a 6 min lock-out interval and no background infusion.

Evidence for comparator: -

Actual start date of recruitment	01 June 2015
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: 150
Worldwide total number of subjects	150
EEA total number of subjects	150

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)	106
From 65 to 84 years	44

85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Eligible subjects were Danish speaking adults scheduled for acute internal fixation of an ankle fracture in two university hospitals in Copenhagen, Denmark. Treating physicians consecutively identify eligible subjects according to the listed criteria.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	PNB anaesthesia

Arm description: -

Arm type	Experimental
Investigational medicinal product name	ropivacaine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Perineural use

Dosage and administration details:

Ultrasound guided popliteal sciatic nerve block: Ropivacaine 7,5 mg/ml, 20 ml
Ultrasound guided saphenous nerve block: Ropivacaine 7,5 mg/ml, 8 ml

Arm title	Spinal anasthesia

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	hyperbaric bupivacaine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in vial
Routes of administration	Intrathecal use

Dosage and administration details:

Spinal anaesthesia: Hyperbaric bupivacaine 5 mg/ml, 2 ml.

Number of subjects in period 1	PNB anaesthesia	Spinal anasthesia
Started	77	73
Completed	77	73

Baseline characteristics

Reporting groups	
Reporting group title	PNB anaesthesia
Reporting group description: -	
Reporting group title	Spinal anasthesia
Reporting group description: -	

Reporting group values	PNB anaesthesia	Spinal anasthesia	Total
Number of subjects	77	73	150
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			
median	56	54	
inter-quartile range (Q1-Q3)	43.5 to 65.5	40 to 67	-
Gender categorical Units: Subjects			
Female	51	46	97
Male	26	27	53

End points

End points reporting groups

Reporting group title	PNB anaesthesia
Reporting group description: -	
Reporting group title	Spinal anasthesia
Reporting group description: -	

Primary: PIOC (pain intensity and opioid consumption) score

End point title	PIOC (pain intensity and opioid consumption) score
End point description:	
End point type	Primary
End point timeframe:	
0-27 hours post-anaesthesia	

End point values	PNB anaesthesia	Spinal anasthesia		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	77	73		
Units: %				
median (standard deviation)	-26.5 (± 87.4)	54.3 (± 93.6)		

Statistical analyses

Statistical analysis title	PIOC analysis
Statistical analysis description:	
PIOC is calculated by ranking both the NRS area under the curve (AUC) pain score and total morphine consumption 0-27 hours across both groups. PIOC is the summation of the deviations from the mean ranks for both parameters and equals -200% to +200% for each patient.	
Comparison groups	PNB anaesthesia v Spinal anasthesia
Number of subjects included in analysis	150
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Wilcoxon (Mann-Whitney)

Secondary: Morphine consumption

End point title	Morphine consumption
End point description:	

End point type	Secondary
End point timeframe:	
0-27 hours post-anaesthesia	

End point values	PNB anaesthesia	Spinal anasthesia		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	77	73		
Units: mg i.v.				
median (inter-quartile range (Q1-Q3))	20 (12.5 to 38.8)	32.5 (18.1 to 65)		

Statistical analyses

Statistical analysis title	Morphine consumption comparison
Statistical analysis description:	
Comparison of 0-27 hours morphine consumption.	
Comparison groups	PNB anaesthesia v Spinal anasthesia
Number of subjects included in analysis	150
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Wilcoxon (Mann-Whitney)

Secondary: NRS-AUC pain score

End point title	NRS-AUC pain score
End point description:	

End point type	Secondary
End point timeframe:	
0-27 hours post-anaesthesia	

End point values	PNB anaesthesia	Spinal anasthesia		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	77	73		
Units: NRS*hours				
median (inter-quartile range (Q1-Q3))	37.5 (20.3 to 54)	72 (43.5 to 102)		

Statistical analyses

Statistical analysis title	Pain score comparison
Statistical analysis description: Numeric rating scale (NRS) area under the curve (AUC) 0-27 hours comparison.	
Comparison groups	PNB anaesthesia v Spinal anasthesia
Number of subjects included in analysis	150
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Wilcoxon (Mann-Whitney)

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 20 hours post-anaesthesia	
Assessment type	Systematic

Dictionary used	
Dictionary name	None
Dictionary version	0

Reporting groups	
Reporting group title	PNB anaesthesia
Reporting group description: -	
Reporting group title	Spinal anaesthesia
Reporting group description: -	

Serious adverse events	PNB anaesthesia	Spinal anaesthesia	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 77 (1.30%)	0 / 73 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
General disorders and administration site conditions			
Nausea	Additional description: Severe nausea causing an extra admission day before hospital discharge.		
subjects affected / exposed	1 / 77 (1.30%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	PNB anaesthesia	Spinal anaesthesia	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 77 (7.79%)	14 / 73 (19.18%)	
General disorders and administration site conditions			
Nausea			
subjects affected / exposed	6 / 77 (7.79%)	7 / 73 (9.59%)	
occurrences (all)	6	7	
Renal and urinary disorders			

Urinary retention postoperative subjects affected / exposed occurrences (all)	0 / 77 (0.00%) 0	7 / 73 (9.59%) 7	

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/28576901

http://www.ncbi.nlm.nih.gov/pubmed/33546844