Clinical trial results:
Preoperative analgesic affect of combined obturator and femoral nerve block compared to femoral nerve block alone, in patients with hip fracture.

Summary

EudraCT number	2015-002304-89
Trial protocol	DK
Global end of trial date	09 August 2018

Results information

Result version number	v1 (current)
This version publication date	19 January 2021
First version publication date	19 January 2021

Trial information

Trial identification

Sponsor protocol code	protocol2_2tdn

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Aarhus University Hospital
Sponsor organisation address	Palle Juul-Jensens Boulevard 99, Aarhus, Denmark, 8200
Public contact	Dep. Anaesthesia, Aarhus University Hospital, +45 51542997, tfbe@clin.au.dk
Scientific contact	Dep. Anaesthesia, Aarhus University Hospital, +45 51542997, tfbe@clin.au.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	09 August 2018
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	09 August 2018
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The objective of the trial is to investigate if the combination af a femoral and a obturator nerve block provides better analgesia that a femoral nerve block alone, in patients with hip fracture

Protection of trial subjects:

This trial was conducted in accordance with the Declaration of Helsinki and approved by the Danish Medicines Agency, the Central Denmark Region Commitees on Health Research Ethics. The trial was prospectively registered in the Eudra database and monitored by the Good Clinical Practice Unit at Aalborg and Aarhus University Hospitals. Prior to inclusion written informed consent was obtained from all subject after a thorough oral and written information had been given.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	24 August 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: 26
Worldwide total number of subjects	26
EEA total number of subjects	26

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)	0
From 65 to 84 years	11
85 years and over	15

Subject disposition

Recruitment

Recruitment details:

Patients were recruited at Aarhus University Hospital according to the approved recruitment plan in the protocol.

Pre-assignment

Screening details:

INCLUSION: Suspected hip fracture, age > 54 years, able to follow instructions according to the protocol, arrival to ER at hours where involved anesthesiologists are present, NRS pain score > 3 at rest and > 5 during dynamic examination
EXCLUSION: No hip fracture at X-ray, weight < 40 kg, allergy to local anesthetics, infection in hip area

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Active obturator nerve block

Arm description:

Femoral nerve block with 15 mL bupivacaine 0.25% + obturator nerve block with 20 mL bupivacaine 0.25%

Arm type	Experimental
Investigational medicinal product name	Bupivacaine 0.25%
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Perineural use

Dosage and administration details:

Femoral nerve block with 15 mL and obturator nerve block with 20 mL.

Arm title	Placebo obturator nerve block

Arm description:

Active femoral nerve block and placebo obturator nerve block

Arm type	Placebo
Investigational medicinal product name	Bupivacaine 0.25%
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Perineural use

Dosage and administration details:

Femoral nerve block with 15 mL

Investigational medicinal product name	Sodium chloride 0.9%
Investigational medicinal product code	
Other name	Isotonic saline
Pharmaceutical forms	Solution for injection
Routes of administration	Perineural use

Dosage and administration details:

Obturator nerve block with 20 mL

Number of subjects in period 1[1]	Active obturator nerve block	Placebo obturator nerve block
Started	7	6
Completed	7	6

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: 26 patients were enrolled - 13 patients were excluded before randomization due to the exclusion criteria defined in the protocol.

Baseline characteristics

Reporting groups	
Reporting group title	Overall period
Reporting group description:	
26 patients were enrolled - only 13 completed randomization. 13 were excluded before randomization according to the exclusion criteria defined in the protocol.	

Reporting group values	Overall period	Total	
Number of subjects	13	13	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	0	0	
From 65-84 years	6	6	
85 years and over	7	7	
Gender categorical Units: Subjects			
Female	12	12	
Male	1	1	

End points

End points reporting groups

Reporting group title	Active obturator nerve block
Reporting group description:	
Femoral nerve block with 15 mL bupivacaine 0.25% + obturator nerve block with 20 mL bupivacaine 0.25%	
Reporting group title	Placebo obturator nerve block
Reporting group description:	
Active femoral nerve block and placebo obturator nerve block	

Primary: Succesrate for sufficient analgesia 30 min after nerve block

End point title	Succesrate for sufficient analgesia 30 min after nerve block
End point description:	
End point type	Primary
End point timeframe:	
30 min after nerve block	

End point values	Active obturator nerve block	Placebo obturator nerve block		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	6		
Units: Frequency				
Success	4	2		
Failure	3	4		

Statistical analyses

Statistical analysis title	Success of obturator nerve block
Comparison groups	Placebo obturator nerve block v Active obturator nerve block
Number of subjects included in analysis	13
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.05
Method	Chi-squared

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

30 minutes after obturator nerve block

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	10.0

Reporting groups

Reporting group title	All subjects enrolled

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: No non-serious adverse events occurred. The trial was terminated prematurely and therefore only 26 patients were enrolled and only 13 patients were randomized. One serious adverse event occurred but this adverse event was not related to the trial medication because it occurred after femoral nerve block and before randomization and obturator nerve block.

Serious adverse events	All subjects enrolled		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 26 (3.85%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Cardiac disorders			
Atrial fibrillation	Additional description: Atrial fibrillation after femoral nerve block. Study medication was never given.		
subjects affected / exposed	1 / 26 (3.85%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 0.05 %

Non-serious adverse events	All subjects enrolled		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 26 (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? Yes

Date	Interruption	Restart date
09 August 2018	Inability to include a sufficient number of patients	-

Notes:

Limitations and caveats

None reported