Clinical trial results:
Analgesic effect of proximal supplemental obturator nerve block after insufficient analgesic effect of femoral nerve block in patients with hip fracture.

Summary

EudraCT number	2015-000078-36
Trial protocol	DK
Global end of trial date	27 August 2015

Results information

Result version number	v1 (current)
This version publication date	21 January 2021
First version publication date	21 January 2021

Trial information

Trial identification

Sponsor protocol code	protocol2tdn

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 N, Denmark, 8200
Public contact	Dep. Anaesthesia, Aarhus University Hospital, +45 28782877, thomas.dahl.nielsen@clin.au.dk
Scientific contact	Dep. Anaesthesia, Aarhus University Hospital, +45 28782877, thomas.dahl.nielsen@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	27 August 2015
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	27 August 2015
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The objective of the trail is to investigate if supplementing an insufficient femoral nerve block with an obturator nerve block has analgesic effect in patients with hip fracture

Protection of trial subjects:

No trial subjects were included.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 March 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: 1
Worldwide total number of subjects	1
EEA total number of subjects	1

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	0
85 years and over	1

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Inclusion: suspected hip fracture, successful sensory anesthesia after femoral nerve block, age >55, capable of cooperation, NRS > 3 at rest or >5 by passive straight leg lift 30 min after femoral nerve block.
Exclusion: No hip fracture at x-ray, weight <45 kg, allergy to local anesthetic, infection in the area of nerve block.

Period 1

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

Blinding implementation details:

The trial was designed as a randomized, controlled, doubled-blinded trial, but he trial was never started.

Arms

Arm title	Overall trial

Arm description:

The trial was never started and therefore no patients were enrolled. The trial was planned to be a randomized, controlled, double-blind trial with two arms. It is stated that one patient started this arm "overall trial", however this was only to be able to post and finalize the study in EudraCT, as the system will not accept at value of zero.
In the protocol it was described that all patients with hip fracture would receive a femoral nerve block and after that patients would be randomized to receive an obturator nerve block with bupivacaine or saline.

Arm type	Trial not started, no patients were randomized
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:

Planned per protocol: femoral nerve block with 15 mL bupivacaine and active obturator nerve block 15 mL bupivacaine

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

Dosage and administration details:

Planned per protocol: placebo obturator nerve block with 15 mL

Number of subjects in period 1	Overall trial
Started	1
Completed	0
Not completed	1
Protocol deviation	1

Baseline characteristics

End points

End points reporting groups

Reporting group title	Overall trial

Reporting group description:

The trial was never started and therefore no patients were enrolled. The trial was planned to be a randomized, controlled, double-blind trial with two arms. It is stated that one patient started this arm "overall trial", however this was only to be able to post and finalize the study in EudraCT, as the system will not accept at value of zero.
In the protocol it was described that all patients with hip fracture would receive a femoral nerve block and after that patients would be randomized to receive an obturator nerve block with bupivacaine or saline.

Primary: Frequency of sufficient analgesia 20 minutes after supplemental obturator nerve block

End point title	Frequency of sufficient analgesia 20 minutes after supplemental obturator nerve block[1]

End point description:

This was the primary outcome as defined in the protocol. Per protocol the primary outcome would compare the group with active and placebo obturator nerve block.
No patients were enrolled in the trial and the trial was ended prematurely before any data were collected.

End point type	Primary

End point timeframe:

20 minutes after obturator nerve block

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: No data were collected for the primary end point and therefore no statistical analyses were performed. The trial was ended prematurely before any patients were enrolled.

End point values	Overall trial			
Subject group type	Reporting group			
Number of subjects analysed	0[2]			
Units: frequency				
Success Failure				

Notes:

[2] - The trial was ended prematurely, no patients were enrolled.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

Timeframe defined in the protocol: 30 min after nerve block.
No patients were included.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	10.0

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

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: The trial was ended prematurely before any patients were enrolled.

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
27 August 2015	The trial was prematurely terminated as it was not possible to recruit any patients. No patients were enrolled before termination.	-

Notes:

Limitations and caveats

None reported