Clinical trial results:
Analgesic duration of a preoperative single-shot femoral nerve block with Bupivacaine and adjuvant Dexamethasone in patients with hip fracture

Summary

EudraCT number	2014-001702-18
Trial protocol	DK
Global end of trial date	27 August 2015

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	protocol1tdn

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 is to investigate if the addition of Dexamethasone to Bupivacaine for preoperative analgesia with a femoral nerve block in patients with hip fracture results in prolonged analgesia compared to plain Bupivacaine without Dexamethasone

Protection of trial subjects:

This trial was conducted in accordance with the Declaration of Helsinki. The trial was approved by the Danish Medicines Agency, the Central Denmark Region Committees on Health Research Ethics, and the Danish Data Protection Agency. The trial was monitored by the Good Clinical Practice Unit at Aarhus and Aalborg University Hospitals. Prior to inclusion, written informed consent was obtained from the patients.

Background therapy: -	
Evidence for comparator: -	
Actual start date of recruitment	01 January 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: 3
Worldwide total number of subjects	3
EEA total number of subjects	3

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	3

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

INCLUSION: Suspected hip fracture, age > 50 yrs, capable of following instructions per protocol, arrival to ER at hours where anesthesiologists involved in the study are present, NRS pain score > 4 at time of inclusion.
EXCLUSION: No hip fracture at X-ray, weight < 40 kg.

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	Protracted femoral nerve block

Arm description:

Bupivacaine 0.5% + adrenaline 5 microgram/mL, 15 mL + 8 mg (2 mL) dexamethasone for femoral nerve block

Arm type	Experimental
Investigational medicinal product name	Bupivacaine 0.5% + adrenaline 5 micrograms/mL
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Perineural use

Dosage and administration details:

Bupivacaine 0.5% + adrenaline 5 micrograms/mL, 15 mL

Investigational medicinal product name	Dexamethasone 4 mg/mL
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Perineural use

Dosage and administration details:

2 mL for femoral nerve block.

Arm title	Plain femoral nerve block

Arm description: -

Arm type	Control
Investigational medicinal product name	Bupivacaine 0.5% + adrenaline 5 micrograms/mL
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Perineural use

Dosage and administration details:

Bupivacaine 0.5% + adrenaline 5 micrograms/mL, 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:

2 mL for femoral nerve block.

Number of subjects in period 1	Protracted femoral nerve block	Plain femoral nerve block
Started	2	1
Completed	0	0
Not completed	2	1
Protocol deviation	2	1

Baseline characteristics

Reporting groups	
Reporting group title	Overall period

Reporting group description: -

Reporting group values	Overall period	Total	
Number of subjects	3	3	
Age categorical Units: Subjects			
85 years and over	3	3	
Gender categorical Units: Subjects			
Female	3	3	
Male	0	0	

End points

End points reporting groups

Reporting group title	Protracted femoral nerve block

Reporting group description:

Bupivacaine 0.5% + adrenaline 5 microgram/mL, 15 mL + 8 mg (2 mL) dexamethasone for femoral nerve block

Reporting group title	Plain femoral nerve block

Reporting group description: -

Primary: Success rate of analgesia

End point title	Success rate of analgesia[1]

End point description:

Success is defined as minimum 24 hours of analgesia after femoral nerve block.

End point type	Primary

End point timeframe:

24 hours after 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: The trial was terminated prematurely before any data regarding endpoints were collected. Therefore no statistical analysis could be performed.

End point values	Protracted femoral nerve block	Plain femoral nerve block		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[2]	0[3]		
Units: frequency				
Success				
Failure				

Notes:

[2] - No statistical analysis performed due to early termination.

[3] - No statistical analysis performed due to early termination.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: 24 hours after femoral nerve block.	
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 terminated prematurely. Only three patients were enrolled and none of them received the randomized treatment.

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	Recruitment was not feasible	-

Notes:

Limitations and caveats

None reported