



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