



## Clinical trial results:

**Does perineural dexmedetomidine prolong the duration of an adductor canal block**

**when controlling for a systemic effect?**

**- a randomized, blinded, paired study in healthy volunteers**

### Summary

|                          |                   |
|--------------------------|-------------------|
| EudraCT number           | 2014-005651-89    |
| Trial protocol           | DK                |
| Global end of trial date | 09 September 2015 |

### Results information

|                                |                  |
|--------------------------------|------------------|
| Result version number          | v1 (current)     |
| This version publication date  | 22 December 2021 |
| First version publication date | 22 December 2021 |

### Trial information

#### Trial identification

|                       |             |
|-----------------------|-------------|
| Sponsor protocol code | SM2-JH-2014 |
|-----------------------|-------------|

#### Additional study identifiers

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

Notes:

### Sponsors

|                              |   |
|------------------------------|---|
| Sponsor organisation name    | Zealand University Hospital   |
| Sponsor organisation address | Lykkebækvej 1, Koege, Denmark, 4600   |
| Public contact               | Clinical trials information, Køge Sygehus, 0045 60610666, hessel@dadlnet.dk |
| Scientific contact           | Clinical trials information, Køge Sygehus, 0045 60610666, hessel@dadlnet.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                       | 01 October 2015   |
| Is this the analysis of the primary completion data? | Yes               |
| Primary completion date                              | 09 September 2015 |
| Global end of trial reached?                         | Yes               |
| Global end of trial date                             | 09 September 2015 |
| Was the trial ended prematurely?                     | No                |

Notes:

## General information about the trial

Main objective of the trial:

To investigate whether dexmedetomidine as an adjuvant to ropivacaine for adductor canal block increases duration of the sensory block when controlling for a systemic effect

Protection of trial subjects:

All nerve blocks were performed by a trained anesthesiologist

Background therapy: -

Evidence for comparator: -

|   |             |
|---|-------------|
| Actual start date of recruitment                          | 01 May 2015 |
| Long term follow-up planned                               | No          |
| Independent data monitoring committee (IDMC) involvement? | Yes         |

Notes:

## Population of trial subjects

### Subjects enrolled per country

|                                      |             |
|--------------------------------------|-------------|
| Country: Number of subjects enrolled | Denmark: 42 |
| Worldwide total number of subjects   | 42          |
| EEA total number of subjects         | 42          |

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)                      | 42 |
| From 65 to 84 years                       | 0  |
| 85 years and over                         | 0  |

## Subject disposition

### Recruitment

Recruitment details:

Patients very healthy volunteers recruited in the medical School of Copenhagen medical bulletin.

### Pre-assignment

Screening details:

Eligible volunteers were males, more than 18 years old, and had American Society of Anesthesiologists physical status I.

Exclusion criteria were inability to read and speak Danish, allergies to the involved drugs, weekly alcohol consumption of more than 21 units, medical abuse, use of any analgesics within 48 h or consumption of opioids within

### Period 1

|                              |   |
|------------------------------|---|
| Period 1 title               | baseline  |
| 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 |
|------------------------------|-----|

|                  |            |
|------------------|------------|
| <b>Arm title</b> | Ropi + dex |
|------------------|------------|

Arm description: -

|  |                 |
|--|-----------------|
| Arm type                               | Experimental    |
| Investigational medicinal product name | Dexmedetomidine |
| Investigational medicinal product code |                 |
| Other name                             |                 |
| Pharmaceutical forms                   | Injection       |
| Routes of administration               | Perineural use  |

Dosage and administration details:

100ug perineurally

|                  |                |
|------------------|----------------|
| <b>Arm title</b> | Ropi + placebo |
|------------------|----------------|

Arm description: -

|  |                |
|--|----------------|
| Arm type                               | Placebo        |
| Investigational medicinal product name | saline         |
| Investigational medicinal product code |                |
| Other name                             |                |
| Pharmaceutical forms                   | Injection      |
| Routes of administration               | Perineural use |

Dosage and administration details:

1ml

| Number of subjects in period 1 | Ropi + dex | Ropi + placebo |
|--------------------------------|------------|----------------|
| Started                        | 21         | 21             |
| Completed                      | 21         | 21             |

## Period 2

|                              |   |
|------------------------------|---|
| Period 2 title               | overall trial   |
| Is this the baseline period? | No  |
| Allocation method            | Randomised - controlled                                       |
| Blinding used                | Double blind  |
| Roles blinded                | Investigator, Monitor, Data analyst, Subject, Carer, Assessor |

## Arms

|                              |                |
|------------------------------|----------------|
| Are arms mutually exclusive? | Yes            |
| <b>Arm title</b>             | Ropi + placebo |

Arm description: -

|  |                |
|--|----------------|
| Arm type                               | Placebo        |
| Investigational medicinal product name | ropivacaine    |
| Investigational medicinal product code |                |
| Other name                             |                |
| Pharmaceutical forms                   | Injection      |
| Routes of administration               | Perineural use |

Dosage and administration details:

150mg

|                  |            |
|------------------|------------|
| <b>Arm title</b> | Ropi + dex |
|------------------|------------|

Arm description: -

|  |                 |
|--|-----------------|
| Arm type                               | Experimental    |
| Investigational medicinal product name | Dexmedetomidine |
| Investigational medicinal product code |                 |
| Other name                             |                 |
| Pharmaceutical forms                   | Injection       |
| Routes of administration               | Perineural use  |

Dosage and administration details:

100ug

| Number of subjects in period 2 | Ropi + placebo | Ropi + dex |
|--------------------------------|----------------|------------|
| Started                        | 21             | 21         |
| Completed                      | 21             | 21         |



## Baseline characteristics

### Reporting groups

|                       |          |
|-----------------------|----------|
| Reporting group title | baseline |
|-----------------------|----------|

Reporting group description: -

| Reporting group values   | baseline       | Total |  |
|--|----------------|-------|--|
| Number of subjects   | 42             | 42    |  |
| Age categorical<br>Units: Subjects                               |                |       |  |
| Age continuous<br>Units: years<br>median<br>full range (min-max) | 23<br>19 to 27 | -     |  |
| Gender categorical<br>Units: Subjects                            |                |       |  |
| Female   | 0              | 0     |  |
| Male   | 42             | 42    |  |

## End points

### End points reporting groups

|                                |                |
|--------------------------------|----------------|
| Reporting group title          | Ropi + dex     |
| Reporting group description: - |                |
| Reporting group title          | Ropi + placebo |
| Reporting group description: - |                |
| Reporting group title          | Ropi + placebo |
| Reporting group description: - |                |
| Reporting group title          | Ropi + dex     |
| Reporting group description: - |                |

### Primary: duration of sensory nerve block assessed by temperature discrimination

|                        |  |
|------------------------|--|
| End point title        | duration of sensory nerve block assessed by temperature discrimination |
| End point description: |  |
| End point type         | Primary  |
| End point timeframe:   |  |
| 0-48h                  |  |

| End point values                          | Ropi + placebo  | Ropi + dex      |  |  |
|---|-----------------|-----------------|--|--|
| Subject group type                        | Reporting group | Reporting group |  |  |
| Number of subjects analysed               | 21              | 21              |  |  |
| Units: hours                              |                 |                 |  |  |
| arithmetic mean (confidence interval 95%) | 20 (19 to 21)   | 22 (21 to 23)   |  |  |

### Statistical analyses

|   |                             |
|---|-----------------------------|
| Statistical analysis title              | paired t test               |
| Statistical analysis description:       |                             |
| paired t test                           |                             |
| Comparison groups                       | Ropi + placebo v Ropi + dex |
| Number of subjects included in analysis | 42                          |
| Analysis specification                  | Pre-specified               |
| Analysis type                           | superiority                 |
| P-value                                 | = 0.05                      |
| Method                                  | t-test, 2-sided             |

### Secondary: duration of sensory nerve block assessed by pinprick

|                        |  |
|------------------------|--|
| End point title        | duration of sensory nerve block assessed by pinprick |
| End point description: |  |
| End point type         | Secondary  |
| End point timeframe:   |  |
| 0-48h                  |  |

|   |                 |                 |  |  |
|---|-----------------|-----------------|--|--|
| <b>End point values</b>                   | Ropi + placebo  | Ropi + dex      |  |  |
| Subject group type                        | Reporting group | Reporting group |  |  |
| Number of subjects analysed               | 21              | 21              |  |  |
| Units: hours                              |                 |                 |  |  |
| arithmetic mean (confidence interval 95%) | 20 (19 to 21)   | 22 (21 to 23)   |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: duration of sensory nerve block assessed pain during tonic heat stimulation

|                        |   |
|------------------------|---|
| End point title        | duration of sensory nerve block assessed pain during tonic heat stimulation |
| End point description: |   |
| End point type         | Secondary   |
| End point timeframe:   |   |
| 0-48h                  |   |

|   |                 |                 |  |  |
|---|-----------------|-----------------|--|--|
| <b>End point values</b>                   | Ropi + placebo  | Ropi + dex      |  |  |
| Subject group type                        | Reporting group | Reporting group |  |  |
| Number of subjects analysed               | 21              | 21              |  |  |
| Units: hours                              |                 |                 |  |  |
| arithmetic mean (confidence interval 95%) | 20 (19 to 21)   | 22 (21 to 23)   |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: duration of nerve block assessed by warmth detection threshold

|                 |  |
|-----------------|--|
| End point title | duration of nerve block assessed by warmth detection threshold |
|-----------------|--|



End point description:

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

0-48h

| End point values                          | Ropi + placebo  | Ropi + dex      |  |  |
|---|-----------------|-----------------|--|--|
| Subject group type                        | Reporting group | Reporting group |  |  |
| Number of subjects analysed               | 21              | 21              |  |  |
| Units: hours                              |                 |                 |  |  |
| arithmetic mean (confidence interval 95%) | 21 (20 to 22)   | 23 (21 to 24)   |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: duration of sensory nerve block assessed by heat pain detection threshold

|                 |   |
|-----------------|---|
| End point title | duration of sensory nerve block assessed by heat pain detection threshold |
|-----------------|---|

End point description:

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

0-48

| End point values                          | Ropi + placebo  | Ropi + dex      |  |  |
|---|-----------------|-----------------|--|--|
| Subject group type                        | Reporting group | Reporting group |  |  |
| Number of subjects analysed               | 21              | 21              |  |  |
| Units: hours                              |                 |                 |  |  |
| arithmetic mean (confidence interval 95%) | 20 (19 to 21)   | 21 (20 to 22)   |  |  |

### Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

0-48 h

|                 |                |
|-----------------|----------------|
| Assessment type | Non-systematic |
|-----------------|----------------|

### Dictionary used

|                 |        |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

|                    |   |
|--------------------|---|
| Dictionary version | 1 |
|--------------------|---|

### Reporting groups

|                       |                  |
|-----------------------|------------------|
| Reporting group title | all participants |
|-----------------------|------------------|

Reporting group description: -

| Serious adverse events                            | all participants |  |  |
|---|------------------|--|--|
| Total subjects affected by serious adverse events |                  |  |  |
| subjects affected / exposed                       | 0 / 42 (0.00%)   |  |  |
| number of deaths (all causes)                     | 0                |  |  |
| number of deaths resulting from adverse events    | 0                |  |  |

Frequency threshold for reporting non-serious adverse events: 1 %

| Non-serious adverse events                            | all participants  |  |  |
|---|---|--|--|
| Total subjects affected by non-serious adverse events |   |  |  |
| subjects affected / exposed                           | 2 / 42 (4.76%)  |  |  |
| Cardiac disorders                                     |   |  |  |
| Bradycardia   | Additional description: bradycardia requiring medical treatment |  |  |
| subjects affected / exposed                           | 2 / 42 (4.76%)  |  |  |
| occurrences (all)                                     | 2   |  |  |

## **More information**

### **Substantial protocol amendments (globally)**

Were there any global substantial amendments to the protocol? No

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### **Interruptions (globally)**

Were there any global interruptions to the trial? No

### **Limitations and caveats**

None reported