# Clinical trial results:
# Suprascapular nerve block as postoperative analgesia after artroscopic shoulder surgery - a randomized, blinded, placebo controlled trial.

## Summary

| | |
|---|---|
| EudraCT number | 2015-002391-24 |
| Trial protocol | DK |
| Global end of trial date | 27 August 2018 |

**Results information**

| | |
|---|---|
| Result version number | v1 (current) |
| This version publication date | 26 December 2020 |
| First version publication date | 26 December 2020 |

## Trial information

**Trial identification**

| | |
|---|---|
| Sponsor protocol code | SSNBCSH01 |

**Additional study identifiers**

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

Notes:

**Sponsors**

| | |
|---|---|
| Sponsor organisation name | Nordsjællands Hospital |
| Sponsor organisation address | Dyrehavevej 29, Hillerød, Denmark, 3400 |
| Public contact | Kai Henrik Wiborg Lange, Nordsjaellands Hospital, kai.henrik.wiborg.lange@regionh.dk |
| Scientific contact | Department of Anaesthesiology, Nordsjaellands Hospital, kai.henrik.wiborg.lange@regionh.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 | 29 August 2018 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 27 August 2018 |
| Global end of trial reached? | Yes |
| Global end of trial date | 27 August 2018 |
| Was the trial ended prematurely? | No |

Notes:

## General information about the trial

Main objective of the trial:

The objective of this study is to examine the reduction in postoperative pain after arthroscopic shoulder surgery in patients treated with a suprascapular nerve block.

Protection of trial subjects:

Standard postoperative care at the Postoperative Care Unit.

Treatment of pain:
Active Group: Nerve block and PCA-pump with morphine
Placebo Group: PCA-pump with morphine

PCA = Patient-controlled analgesia.

Background therapy: -

Evidence for comparator: -

| | |
|---|---|
| Actual start date of recruitment | 01 August 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: 40 |
| Worldwide total number of subjects | 40 |
| EEA total number of subjects | 40 |

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) | 34 |
| From 65 to 84 years | 6 |

| | |
|---|---|
| 85 years and over | 0 |

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details: -

### Pre-assignment period milestones

| | |
|---|---|
| Number of subjects started | 40 |
| Number of subjects completed | 40 |

### Period 1

| | |
|---|---|
| Period 1 title | Overall trial (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 group |

Arm description:

Suprascapular nerve block with active drug (Ropivacaine 7.5 mg*ml-1)

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Ropivacaine |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Perineural use |

Dosage and administration details:

Administered perineurally in relation to the suprascapular nerve as a single shot bolus of 5 ml Ropivacaine 7.5 mg*ml-1

| | |
|---|---|
| **Arm title** | Placebo group |

Arm description:

Suprascapular nerve block with placebo (Saline 9 mg*ml-1)

| | |
|---|---|
| Arm type | Placebo |
| Investigational medicinal product name | Saline |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Perineural use |

Dosage and administration details:

Administered perineurally in relation to the suprascapular nerve as a single shot bolus of 5 ml Saline 9 mg*ml-1

| **Number of subjects in period 1** | Active group | Placebo group |
|---|---|---|
| Started | 20 | 20 |
| Completed | 20 | 20 |

## Baseline characteristics

| Reporting groups | |
|---|---|
| Reporting group title | Active group |
| Reporting group description: | |
| Suprascapular nerve block with active drug (Ropivacaine 7.5 mg*ml-1) | |
| Reporting group title | Placebo group |
| Reporting group description: | |
| Suprascapular nerve block with placebo (Saline 9 mg*ml-1) | |

| Reporting group values | Active group | Placebo group | Total |
|---|---|---|---|
| Number of subjects | 20 | 20 | 40 |
| Age categorical | | | |
| Units: Subjects | | | |
| In utero | | | 0 |
| Preterm newborn infants (gestational age < 37 wks) | | | 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 65-84 years | | | 0 |
| 85 years and over | | | 0 |
| Age continuous | | | |
| Units: years | | | |
| arithmetic mean | 51.6 | 54.3 | |
| standard deviation | ± 10.3 | ± 9.6 | - |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 13 | 9 | 22 |
| Male | 7 | 11 | 18 |
| Height | | | |
| Units: cm | | | |
| arithmetic mean | 173.1 | 174.5 | |
| standard deviation | ± 8.3 | ± 11.2 | - |
| Weight | | | |
| Units: kg | | | |
| arithmetic mean | 84.7 | 88.6 | |
| standard deviation | ± 13.3 | ± 19.1 | - |

## End points

| End points reporting groups | |
|---|---|
| Reporting group title | Active group |
| Reporting group description: | |
| Suprascapular nerve block with active drug (Ropivacaine 7.5 mg*ml-1) | |
| Reporting group title | Placebo group |
| Reporting group description: | |
| Suprascapular nerve block with placebo (Saline 9 mg*ml-1) | |

| Primary: VAS reduction at T30 | |
|---|---|
| End point title | VAS reduction at T30 |
| End point description: | |
| Change in pain score (VAS 0-100mm) from baseline to T30 (30 minutes after application of nerve block) | |
| End point type | Primary |
| End point timeframe: | |
| From Baseline to T30 | |

| End point values | Active group | Placebo group | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 20 | 20 | | |
| Units: VAS | | | | |
| arithmetic mean (standard deviation) | -50.2 (± 17.9) | -26.8 (± 9.9) | | |

### Statistical analyses

| Statistical analysis title | VAS score reduction from baseline to T30 |
|---|---|
| Comparison groups | Active group v Placebo group |
| Number of subjects included in analysis | 40 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | t-test, 2-sided |

| Secondary: VAS AUC T30-T360 during maximum abduction | |
|---|---|
| End point title | VAS AUC T30-T360 during maximum abduction |
| End point description: | |
| VAS score at maximum active abduction of the shoulder ½-6 hours after injection measured as area under the curve (T30-T360; AUC) | |
| End point type | Secondary |

End point timeframe:
From T30-T360

| **End point values** | Active group | Placebo group | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 20 | 20 | | |
| Units: VAS | | | | |
| arithmetic mean (standard deviation) | 134.0 (± 133.3) | 229.1 (± 93.4) | | |

**Statistical analyses**

| **Statistical analysis title** | AUC T30-T360 abduction |
|---|---|
| Comparison groups | Active group v Placebo group |
| Number of subjects included in analysis | 40 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.013 |
| Method | t-test, 2-sided |

**Secondary: AUC T30-T360 at rest**

| End point title | AUC T30-T360 at rest |
|---|---|

End point description:

VAS score at maximum active abduction of the shoulder ½-6 hours after injection measured as area under the curve (T30-T360; AUC)

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

End point timeframe:
T30-T360

| **End point values** | Active group | Placebo group | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 20 | 20 | | |
| Units: VAS | | | | |
| arithmetic mean (standard deviation) | 59.5 (± 80.2) | 134.6 (± 92.0) | | |

**Statistical analyses**

| Statistical analysis title | AUC T30-T360 rest |
|---|---|
| Comparison groups | Active group v Placebo group |
| Number of subjects included in analysis | 40 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.01 |
| Method | t-test, 2-sided |

## Secondary: Total morphine usage T0-T360

| End point title | Total morphine usage T0-T360 |
|---|---|

End point description:

Total use of morphine from 0-6 hours after injection (T0-T360)

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

End point timeframe:

T0-T360

| End point values | Active group | Placebo group | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 20 | 20 | | |
| Units: mg | | | | |
| arithmetic mean (standard deviation) | 6.5 (± 8.4) | 18.5 (± 15.7) | | |

### Statistical analyses

| Statistical analysis title | Morphine T0-T360 |
|---|---|
| Comparison groups | Active group v Placebo group |
| Number of subjects included in analysis | 40 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.01 |
| Method | t-test, 2-sided |

## Secondary: Change in infraspinatus sEMG from baseline to T30

| End point title | Change in infraspinatus sEMG from baseline to T30 |
|---|---|

End point description:

Change in activity of the infraspinatus muscle during maximum voluntary isometric contraction from baseline to T30 measured with surface EMG (sEMG)

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

End point timeframe:

From baseline to 30 minutes after injection (T30)

| End point values | Active group | Placebo group | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 0[1] | 0[2] | | |
| Units: mV | | | | |
| arithmetic mean (standard deviation) | () | () | | |

Notes:

[1] - sEMG signals too poor to analyze

[2] - sEMG signals too poor to analyze

### Statistical analyses

No statistical analyses for this end point

## Secondary: Change in external rotation shoulder strength from baseline to T30

| End point title | Change in external rotation shoulder strength from baseline to T30 |
|---|---|

End point description:

Percentage change in maximum voluntary isometric contraction during external rotation of the shoulder from baseline to 30 minutes after injection (T30) measured with a handheld dynamometer.

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

End point timeframe:

From baseline measurements to 30 minuters after injection (T30)

| End point values | Active group | Placebo group | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 20 | 20 | | |
| Units: mV | | | | |
| arithmetic mean (standard deviation) | -68.9 (± 26.9) | 9.1 (± 23.0) | | |

### Statistical analyses

| Statistical analysis title | Change in external rotation strength T0-T30 |
|---|---|
| Comparison groups | Active group v Placebo group |
| Number of subjects included in analysis | 40 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | t-test, 2-sided |

## Secondary: Change in abduction shoulder strength from baseline to T30

| End point title | Change in abduction shoulder strength from baseline to T30 |
|---|---|

End point description:

Percentage change in maximum voluntary isometric contraction during abduction of the shoulder from baseline to 30 minutes after injection (T30) measured with a handheld dynamometer.

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

End point timeframe:

From baseline to T30

| **End point values** | Active group | Placebo group | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 20 | 20 | | |
| Units: mV | | | | |
| arithmetic mean (standard deviation) | -18.9 (± 44.9) | 27.9 (± 37.4) | | |

**Statistical analyses**

| **Statistical analysis title** | Change in abduction strength T0-T30 |
|---|---|
| Comparison groups | Active group v Placebo group |
| Number of subjects included in analysis | 40 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.001 |
| Method | t-test, 2-sided |

## Adverse events

| Adverse events information[1] | |
|---|---|
| Timeframe for reporting adverse events: 24th november 2015 - 27th august 2018 | |
| Assessment type | Systematic |

| Dictionary used | |
|---|---|
| Dictionary name | SNOMED CT |
| Dictionary version | DK 2015 |

| Reporting groups | |
|---|---|
| Reporting group title | Ropivacaine 7.5 mg*ml-1 |
| Reporting group description: - | |
| Reporting group title | Saline 9 mg*ml-1 |
| Reporting group description: - | |

| Serious adverse events | Ropivacaine 7.5 mg*ml-1 | Saline 9 mg*ml-1 | |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 20 (0.00%) | 0 / 20 (0.00%) | |
| number of deaths (all causes) | 0 | 0 | |
| number of deaths resulting from adverse events | 0 | 0 | |

Frequency threshold for reporting non-serious adverse events: 5 %

| Non-serious adverse events | Ropivacaine 7.5 mg*ml-1 | Saline 9 mg*ml-1 | |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 0 / 20 (0.00%) | 0 / 20 (0.00%) | |

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 recorded during the study period.

## 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? No

## Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

| |
|---|
| Unable to analyze surface electromyography (sEMG) data due to very poor sEMG signals. |

Notes: