# Clinical trial results:
# Supraclavicular catheter for regional anesthesia of the shoulder - an explorative study in healthy volunteers.

## Summary

| | |
|---|---|
| EudraCT number | 2016-002835-14 |
| Trial protocol | DK |
| Global end of trial date | 24 August 2017 |

**Results information**

| | |
|---|---|
| Result version number | v1 (current) |
| This version publication date | 15 March 2021 |
| First version publication date | 15 March 2021 |

## Trial information

**Trial identification**

| | |
|---|---|
| Sponsor protocol code | SCCCSH01 |

**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 | Department of anesthesiology, Nordsjællands Hospital Hillerød, kai.henrik.wiborg.lange@regionh.dk |
| Scientific contact | Department of anesthesiology, Nordsjællands Hospital Hillerød, 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 | 28 August 2017 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 24 August 2017 |
| Global end of trial reached? | Yes |
| Global end of trial date | 24 August 2017 |
| Was the trial ended prematurely? | No |

Notes:

## General information about the trial

Main objective of the trial:

The objective of the trial is to place a supraclavicular catheter in 32 healthy volunteers and examine:
1: If the largest shoulder nerves are affected
2: which other nerves are affected
after injection with a low (5ml) or a high (20 ml) volume of ropivacain 5 mg/ml.

Protection of trial subjects:

Local analgetic skin infiltration before insertion of nerve catheter.

Background therapy: -

Evidence for comparator: -

| | |
|---|---|
| Actual start date of recruitment | 01 July 2017 |
| 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: 32 |
| Worldwide total number of subjects | 32 |
| EEA total number of subjects | 32 |

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) | 32 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

## Subject disposition

| Recruitment | |
|---|---|
| Recruitment details: - | |

| Pre-assignment | |
|---|---|
| Screening details: - | |

| Pre-assignment period milestones | |
|---|---|
| Number of subjects started | 32 |
| Number of subjects completed | 32 |

| 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, Assessor |

| Arms | |
|---|---|
| Are arms mutually exclusive? | Yes |
| **Arm title** | 5 ml Ropivacaine |
| Arm description: - | |
| 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:

5 ml Ropivacaine 5 mg*ml-1 administered perineurally in relation to the brachial plexus at a supraclavicular level.

| **Arm title** | 20 ml ropivacaine |
|---|---|
| Arm description: - | |
| Arm type | Active comparator |
| 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:

20 ml Ropivacaine 5 mg*ml-1 administered perineurally in relation to the brachial plexus at a supraclavicular level.

| **Number of subjects in period 1** | 5 ml Ropivacaine | 20 ml ropivacaine |
|---|---|---|
| Started | 16 | 16 |
| Completed | 16 | 16 |

## Baseline characteristics

| Reporting groups | |
|---|---|
| Reporting group title | 5 ml Ropivacaine |
| Reporting group description: - | |
| Reporting group title | 20 ml ropivacaine |
| Reporting group description: - | |

| Reporting group values | 5 ml Ropivacaine | 20 ml ropivacaine | Total |
|---|---|---|---|
| Number of subjects | 16 | 16 | 32 |
| Age categorical<br>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<br>Units: years | | | |
| arithmetic mean | 24.7 | 25.3 | |
| standard deviation | ± 8.2 | ± 3.2 | - |
| Gender categorical<br>Units: Subjects | | | |
| Female | 9 | 9 | 18 |
| Male | 7 | 7 | 14 |

## End points

| End points reporting groups | |
|---|---|
| Reporting group title | 5 ml Ropivacaine |
| Reporting group description: - | |
| Reporting group title | 20 ml ropivacaine |
| Reporting group description: - | |

| Primary: Shoulder nerve block | |
|---|---|
| End point title | Shoulder nerve block |
| End point description: | |
| End point type | Primary |
| End point timeframe: | |
| From baseline to T45 | |

| End point values | 5 ml Ropivacaine | 20 ml ropivacaine | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 16 | 16 | | |
| Units: Number | 13 | 15 | | |

### Statistical analyses

| Statistical analysis title | Shoulder nerves affected |
|---|---|
| Comparison groups | 5 ml Ropivacaine v 20 ml ropivacaine |
| Number of subjects included in analysis | 32 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority[1] |
| Parameter estimate | Risk difference (RD) |
| Point estimate | -0.13 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.35 |
| upper limit | 0.9 |

Notes:

[1] - Noninferiority margin was based on the lower bound of the 95% confidence interval (CI) for the difference between proportions of succesful shoulder blocks in the 5 ml group vs the 20 ml group being greater than -0.2. As the difference in proportions was above -0.2 and the upper bound of the 95% CI was above zero, our results were inconclusive.

| Secondary: Change in spirometry (VC) | |
|---|---|
| End point title | Change in spirometry (VC) |

| | |
|---|---|
| End point description:<br>The relative change in spirometry (VC) from baseline to 45 minutes after injection of ropivacain 0.5%. | |
| End point type | Secondary |
| End point timeframe:<br>T0-T45 | |

| **End point values** | 5 ml Ropivacaine | 20 ml ropivacaine | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 16 | 16 | | |
| Units: Litres | | | | |
| arithmetic mean (standard deviation) | -2.6 (± 9.8) | -10.6 (± 8.9) | | |

**Statistical analyses**

| **Statistical analysis title** | Change in spirometry (VC) |
|---|---|
| Comparison groups | 5 ml Ropivacaine v 20 ml ropivacaine |
| Number of subjects included in analysis | 32 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.021 |
| Method | t-test, 2-sided |

| **Secondary: Change in spirometry (FVC)** | |
|---|---|
| End point title | Change in spirometry (FVC) |
| End point description:<br>The relative change in spirometry (FVC) from baseline to 45 minutes after injection of ropivacain 0.5%. | |
| End point type | Secondary |
| End point timeframe:<br>T0-T45 | |

| **End point values** | 5 ml Ropivacaine | 20 ml ropivacaine | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 16 | 16 | | |
| Units: Litres | | | | |
| arithmetic mean (standard deviation) | -1.1 (± 8.9) | -6.4 (± 9.3) | | |

**Statistical analyses**

| Statistical analysis title | Change in spirometry (FVC) |
|---|---|
| Comparison groups | 5 ml Ropivacaine v 20 ml ropivacaine |
| Number of subjects included in analysis | 32 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.113 |
| Method | t-test, 2-sided |

## Secondary: Change in spirometry (FEV1)

| End point title | Change in spirometry (FEV1) |
|---|---|
| End point description: | |
| The relative change in spirometry (FEV1) from baseline to 45 minutes after injection of ropivacain 0.5%. | |
| End point type | Secondary |
| End point timeframe: | |
| T0-T45 | |

| End point values | 5 ml Ropivacaine | 20 ml ropivacaine | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 16 | 16 | | |
| Units: Litres | | | | |
| arithmetic mean (standard deviation) | -2.7 (± 9.3) | -8.8 (± 7.1) | | |

### Statistical analyses

| Statistical analysis title | Change in spirometry (FEV1) |
|---|---|
| Comparison groups | 5 ml Ropivacaine v 20 ml ropivacaine |
| Number of subjects included in analysis | 32 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.044 |
| Method | t-test, 2-sided |

## Secondary: Change in spirometry (PEF)

| End point title | Change in spirometry (PEF) |
|---|---|
| End point description: | |
| The relative change in spirometry (PEF) from baseline to 45 minutes after injection of ropivacain 0.5%. | |
| End point type | Secondary |
| End point timeframe: | |
| T0-T45 | |

| End point values | 5 ml Ropivacaine | 20 ml ropivacaine | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 16 | 16 | | |
| Units: Litres per minute | | | | |
| arithmetic mean (standard deviation) | 0.7 (± 15.4) | -6.7 (± 8.8) | | |

**Statistical analyses**

| Statistical analysis title | Change in spirometry (PEF) |
|---|---|
| Comparison groups | 5 ml Ropivacaine v 20 ml ropivacaine |
| Number of subjects included in analysis | 32 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.11 |
| Method | t-test, 2-sided |

**Secondary: Complete phrenic nerve block**

| End point title | Complete phrenic nerve block |
|---|---|
| End point description: | |
| Number of subjects with a complete unilateral phrenic nerve block defined as a reduction in FVC of at least 20%. | |
| End point type | Secondary |
| End point timeframe: | |
| T0-T45 | |

| End point values | 5 ml Ropivacaine | 20 ml ropivacaine | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 16 | 16 | | |
| Units: Number | 0 | 2 | | |

**Statistical analyses**

| Statistical analysis title | Phrenic nerve block |
|---|---|
| Comparison groups | 5 ml Ropivacaine v 20 ml ropivacaine |

| | |
|---|---|
| Number of subjects included in analysis | 32 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.14 |
| Method | Chi-squared |

## Adverse events

| Adverse events information | |
|---|---|
| Timeframe for reporting adverse events: July to september 2017 | |
| Assessment type | Systematic |
| **Dictionary used** | |
| Dictionary name | SNOMED CT |
| Dictionary version | DK 2015 |
| **Reporting groups** | |
| Reporting group title | Adverse events |

Reporting group description: -

| Serious adverse events | Adverse events | | |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | | |
| number of deaths (all causes) | 0 | | |
| number of deaths resulting from adverse events | 0 | | |

Frequency threshold for reporting non-serious adverse events: 0 %

| Non-serious adverse events | Adverse events | | |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | | |
| Nervous system disorders | | | |
| Subjektiv muskelsvaghed | Additional description: Subjective muscle weakness | | |
| subjects affected / exposed | 1 / 32 (3.13%) | | |
| occurrences (all) | 1 | | |

## 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

None reported