



Clinical trial results:

The influence of different doses of local anaesthetics on the sensory distribution of lateral femoral cutaneous nerve block - a randomised, blinded, paired trial in healthy volunteers

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2016-004936-39 |
| Trial protocol | DK |
| Global end of trial date | 09 June 2017 |

Results information

| | |
|--------------------------------|-----------------|
| Result version number | v1 |
| This version publication date | 07 January 2021 |
| First version publication date | 07 January 2021 |

Trial information

Trial identification

| | |
|-----------------------|--------------|
| Sponsor protocol code | SM2-KHT-2016 |
|-----------------------|--------------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT03138668 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | Department of Anesthesiology |
| Sponsor organisation address | Ringstedgade 61, Næstved, Denmark, 4700 |
| Public contact | Office, Department of Anesthesiology, Næstved Hospital, 45 56514002, anaesthesisekretariat@regionsjaelland.dk |
| Scientific contact | Office, Department of Anesthesiology, Næstved Hospital, 45 56514002, anaesthesisekretariat@regionsjaelland.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 | 09 June 2017 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 09 June 2017 |
| Global end of trial reached? | Yes |
| Global end of trial date | 09 June 2017 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To investigate the sensory distribution of a LFCN-block with two different doses

Protection of trial subjects:

The participants were healthy volunteers. Each participant got to blocks, one on each side. There were not taken special measurements regarding pain, as, local anesthesia at the point of injection also would create pain.

The surroundings however were kept quite, and participants had privacy.

Background therapy: -

Evidence for comparator: -

| | |
|---|-------------|
| Actual start date of recruitment | 19 May 2017 |
| 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: 20 |
| Worldwide total number of subjects | 20 |
| EEA total number of subjects | 20 |

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) | 20 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

50 participants were assessed for eligibility, 30 participants were excluded due to not meeting inclusion criteria, not eligible for study dates, declined participation

Pre-assignment period milestones

| | |
|------------------------------|----|
| Number of subjects started | 20 |
| Number of subjects completed | 20 |

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, Data analyst, Assessor |

Arms

| | |
|------------------------------|---------|
| Are arms mutually exclusive? | Yes |
| Arm title | Group A |

Arm description:

LFCN-block with 8 mL ropivacaine 0.75% on their right side and a LFCN-block containing 16 mL ropivacaine 0.75% on the left side.

| | |
|--|------------------------|
| 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:

Dosage 60 mg or 120 mg, given perineural at the lateral femoral cutaneous nerve.

| | |
|------------------|---------|
| Arm title | Group B |
|------------------|---------|

Arm description:

LFCN-block with 16 mL ropivacaine 0.75% on their right side and a LFCN-block containing 8 mL ropivacaine 0.75% on the left side.

| | |
|--|------------------------|
| 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:

Dosage 60 mg or 120 mg, given perineural at the lateral femoral cutaneous nerve.

| Number of subjects in period 1 | Group A | Group B |
|---------------------------------------|---------|---------|
| Started | 11 | 9 |
| Completed | 11 | 9 |

Baseline characteristics

Reporting groups

| | |
|--------------------------------|---------------|
| Reporting group title | Overall trial |
| Reporting group description: - | |

| Reporting group values | Overall trial | Total | |
|---|---------------|-------|--|
| Number of subjects | 20 | 20 | |
| Age categorical | | | |
| Units: Subjects | | | |
| In utero | 0 | 0 | |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | |
| Newborns (0-27 days) | 0 | 0 | |
| Infants and toddlers (28 days-23 months) | 0 | 0 | |
| Children (2-11 years) | 0 | 0 | |
| Adolescents (12-17 years) | 0 | 0 | |
| Adults (18-64 years) | 20 | 20 | |
| From 65-84 years | 0 | 0 | |
| 85 years and over | 0 | 0 | |
| Age continuous | | | |
| Units: years | | | |
| arithmetic mean | 25 | | |
| full range (min-max) | 19 to 49 | - | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 7 | 7 | |
| Male | 13 | 13 | |
| Height | | | |
| Units: cm | | | |
| arithmetic mean | 176 | | |
| full range (min-max) | 164 to 186 | - | |
| Weight | | | |
| Units: kg | | | |
| arithmetic mean | 70 | | |
| full range (min-max) | 55 to 85 | - | |
| Quadriceps femoris, MVIC, right leg | | | |
| Maximum Voluntary Isometric Contraction of quadriceps femoris | | | |
| Units: kg | | | |
| arithmetic mean | 41 | | |
| full range (min-max) | 26 to 58 | - | |
| Quadriceps femoris, MVIC, left leg | | | |
| Maximum Voluntary Isometric Contraction of quadriceps femoris | | | |
| Units: kg | | | |
| arithmetic mean | 44 | | |
| full range (min-max) | 26 to 63 | - | |
| Heat stimulation, VAS, right leg | | | |
| Visual Analogue Score of pain during heat stimulation. | | | |

| | | | |
|--|----------|---|--|
| Units: mm | | | |
| arithmetic mean | 41 | | |
| full range (min-max) | 9 to 96 | - | |
| Heat stimulation, VAS, left leg | | | |
| Visual Analogue Score of pain during heat stimulation. | | | |
| Units: mm | | | |
| arithmetic mean | 44 | | |
| full range (min-max) | 11 to 94 | - | |

End points

End points reporting groups

| | |
|--|---------|
| Reporting group title | Group A |
| Reporting group description: LFCN-block with 8 mL ropivacaine 0.75% on their right side and a LFCN-block containing 16 mL ropivacaine 0.75% on the left side. | |
| Reporting group title | Group B |
| Reporting group description: LFCN-block with 16 mL ropivacaine 0.75% on their right side and a LFCN-block containing 8 mL ropivacaine 0.75% on the left side. | |

Primary: Coverage of posterior incision by temperature discrimination test

| | |
|---|---|
| End point title | Coverage of posterior incision by temperature discrimination test |
| End point description: | |
| End point type | Primary |
| End point timeframe: One hour post block | |

| End point values | Group A | Group B | | |
|---------------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 11 | 9 | | |
| Units: percent | | | | |
| median (inter-quartile range (Q1-Q3)) | 0 (0 to 0) | 0 (0 to 0) | | |

Statistical analyses

| | |
|---|---|
| Statistical analysis title | Difference of Coverage of post incision by temp |
| Statistical analysis description: Diffence of the coverage of posterior incision by temperature discrimination test. | |
| Comparison groups | Group A v Group B |
| Number of subjects included in analysis | 20 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.345 |
| Method | Wilcoxon (Mann-Whitney) |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 0 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 3.5 |

Secondary: Coverage of lateral incision by temperature discrimination test

| | |
|------------------------|---|
| End point title | Coverage of lateral incision by temperature discrimination test |
| End point description: | |
| End point type | Secondary |
| End point timeframe: | |
| One hour post block | |

| End point values | Group A | Group B | | |
|---------------------------------------|-----------------|------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 11 | 9 | | |
| Units: percent | | | | |
| median (inter-quartile range (Q1-Q3)) | 0 (0 to 19.3) | 19.5 (0 to 45.3) | | |

Statistical analyses

| | |
|--|--|
| Statistical analysis title | Difference of Coverage of lateral incision by temp |
| Statistical analysis description: | |
| Diffence of the coverage of lateral incision by temperature discrimination test. | |
| Comparison groups | Group A v Group B |
| Number of subjects included in analysis | 20 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.221 |
| Method | Wilcoxon (Mann-Whitney) |
| Parameter estimate | Median difference (final values) |
| Point estimate | 7.8 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -2.6 |
| upper limit | 24.5 |

Secondary: Coverage of posterior incision by mechanical discrimination test

| | |
|------------------------|--|
| End point title | Coverage of posterior incision by mechanical discrimination test |
| End point description: | |
| End point type | Secondary |
| End point timeframe: | |
| One hour post block | |

| End point values | Group A | Group B | | |
|---------------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 11 | 9 | | |
| Units: percent | | | | |
| median (inter-quartile range (Q1-Q3)) | 0 (0 to 0) | 0 (0 to 0) | | |

Statistical analyses

| | |
|---|---|
| Statistical analysis title | Difference of Coverage of post incision by mech |
| Statistical analysis description: | |
| Diffence of the coverage of posterior incision by mechanical discrimination test. | |
| Comparison groups | Group A v Group B |
| Number of subjects included in analysis | 20 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.715 |
| Method | Wilcoxon (Mann-Whitney) |
| Parameter estimate | Median difference (final values) |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

Secondary: Coverage of lateral incision by mechanical discrimination test

| | |
|------------------------|--|
| End point title | Coverage of lateral incision by mechanical discrimination test |
| End point description: | |
| End point type | Secondary |
| End point timeframe: | |
| On hour post block. | |

| End point values | Group A | Group B | | |
|---------------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 11 | 9 | | |
| Units: percent | | | | |
| median (inter-quartile range (Q1-Q3)) | 0 (0 to 20.3) | 0 (0 to 29.5) | | |

Statistical analyses

| Statistical analysis title | Difference of Coverage of lateral incision by mech |
|--|--|
| Statistical analysis description: Diffence of the coverage of lateral incision by mechanical discrimination test. | |
| Comparison groups | Group A v Group B |
| Number of subjects included in analysis | 20 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.11 |
| Method | Wilcoxon (Mann-Whitney) |
| Parameter estimate | Median difference (final values) |
| Point estimate | 3.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 16.5 |

Secondary: Blocked area assessed by temperature discrimination test

| End point title | Blocked area assessed by temperature discrimination test |
|---|--|
| End point description: | |
| End point type | Secondary |
| End point timeframe: On hour post block. | |

| End point values | Group A | Group B | | |
|--------------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 11 | 9 | | |
| Units: square centimeter | | | | |
| arithmetic mean (standard deviation) | 418 (± 225) | 564 (± 182.7) | | |

Statistical analyses

| | |
|--|--|
| Statistical analysis title | Difference of blocked area, by temp discrimination |
| Statistical analysis description: Difference of blocked area assessed by temperature discrimination test. | |
| Comparison groups | Group A v Group B |
| Number of subjects included in analysis | 20 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.012 |
| Method | t-test, 2-sided |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 146.3 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 35.7 |
| upper limit | 256.9 |

Secondary: Blocked area assessed by mechanical discrimination test

| | |
|--|---|
| End point title | Blocked area assessed by mechanical discrimination test |
| End point description: | |
| End point type | Secondary |
| End point timeframe: One hour post block. | |

| End point values | Group A | Group B | | |
|--------------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 11 | 9 | | |
| Units: square centimeter | | | | |
| arithmetic mean (standard deviation) | 369 (± 211.4) | 461 (± 156) | | |

Statistical analyses

| | |
|---|--|
| Statistical analysis title | Difference of blocked area, by mech discrimination |
| Statistical analysis description: Difference of blocked area assessed by mechanical discrimination test. | |
| Comparison groups | Group A v Group B |

| | |
|---|--------------------------------|
| Number of subjects included in analysis | 20 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.034 |
| Method | t-test, 2-sided |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 92.2 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 7.8 |
| upper limit | 176.6 |

Secondary: Post-block MVIC ≤80% of baseline

| | |
|------------------------|----------------------------------|
| End point title | Post-block MVIC ≤80% of baseline |
| End point description: | |
| End point type | Secondary |
| End point timeframe: | |
| 1 hour post block. | |

| End point values | Group A | Group B | | |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 11 | 9 | | |
| Units: number | 2 | 2 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: No pain during THS at superior portion of posterior incision

| | |
|------------------------|--|
| End point title | No pain during THS at superior portion of posterior incision |
| End point description: | |
| End point type | Secondary |
| End point timeframe: | |
| One hour post block. | |

| End point values | Group A | Group B | | |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 11 | 9 | | |
| Units: number | 0 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: No pain during THS at superior portion of lateral incision

| | |
|-----------------|--|
| End point title | No pain during THS at superior portion of lateral incision |
|-----------------|--|

End point description:

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

End point timeframe:

One hour post block.

| End point values | Group A | Group B | | |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 11 | 9 | | |
| Units: number | 0 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: No pain during THS at inferior portion of posterior incision

| | |
|-----------------|--|
| End point title | No pain during THS at inferior portion of posterior incision |
|-----------------|--|

End point description:

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

End point timeframe:

One hour post block.

| End point values | Group A | Group B | | |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 11 | 9 | | |
| Units: number | 0 | 1 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: No pain during THS at inferior portion of lateral incision

| | |
|-----------------|--|
| End point title | No pain during THS at inferior portion of lateral incision |
|-----------------|--|

End point description:

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

End point timeframe:

One hour post block.

| End point values | Group A | Group B | | |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 11 | 9 | | |
| Units: number | 2 | 2 | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

In the period from admission of the first block until 2 hours after admission of the last block.

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

| | |
|-----------------|---------|
| Dictionary name | ICH-GCP |
|-----------------|---------|

| | |
|--------------------|------------|
| Dictionary version | Revision 2 |
|--------------------|------------|

Reporting groups

| | |
|-----------------------|------------------------|
| Reporting group title | Overall adverse events |
|-----------------------|------------------------|

Reporting group description: -

| Serious adverse events | Overall adverse events | | |
|---|------------------------|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 20 (0.00%) | | |
| number of deaths (all causes) | 0 | | |
| number of deaths resulting from adverse events | | | |

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

| Non-serious adverse events | Overall adverse events | | |
|---|------------------------|--|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 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: In the 2 hours observation periode for adverse events, none were detected, in this group of healthy volunteers.

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