



## Clinical trial results:

### Effect of local anesthetic dose versus volume on block duration of single shot ultrasound-guided axillary brachial plexus block with mepivacaine

#### Summary

|                          |                |
|--------------------------|----------------|
| EudraCT number           | 2012-001704-38 |
| Trial protocol           | NL             |
| Global end of trial date | 18 June 2014   |

#### Results information

|                                |                 |
|--------------------------------|-----------------|
| Result version number          | v1 (current)    |
| This version publication date  | 15 January 2022 |
| First version publication date | 15 January 2022 |

#### Trial information

##### Trial identification

|                       |                 |
|-----------------------|-----------------|
| Sponsor protocol code | NL40000.072.012 |
|-----------------------|-----------------|

##### Additional study identifiers

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

Notes:

#### Sponsors

|                              |   |
|------------------------------|---|
| Sponsor organisation name    | Sint Maartenskliniek  |
| Sponsor organisation address | Hengstdal 3, Ubbergen, Netherlands,   |
| Public contact               | Clinical Trials Information, Sint Maartenskliniek,<br>m.fenten@maartenskliniek.nl |
| Scientific contact           | Clinical Trials Information, Sint Maartenskliniek,<br>m.fenten@maartenskliniek.nl |

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:

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**Results analysis stage**

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|  |                |
|--|----------------|
| Analysis stage                                       | Final          |
| Date of interim/final analysis                       | 03 August 2014 |
| Is this the analysis of the primary completion data? | Yes            |
| Primary completion date                              | 18 June 2014   |
| Global end of trial reached?                         | Yes            |
| Global end of trial date                             | 18 June 2014   |
| Was the trial ended prematurely?                     | No             |

Notes:

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**General information about the trial**

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Main objective of the trial:

The purpose of the present study is to determine the effect of mepivacaine dose and volume on the duration of sensory axillary brachial plexus block (overall and individual nerves).

Protection of trial subjects:

pain treatment according to standard hospital protocol

Background therapy: -

Evidence for comparator: -

|   |               |
|---|---------------|
| Actual start date of recruitment                          | 02 April 2012 |
| Long term follow-up planned                               | No            |
| Independent data monitoring committee (IDMC) involvement? | No            |

Notes:

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**Population of trial subjects**

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**Subjects enrolled per country**

|                                      |                 |
|--------------------------------------|-----------------|
| Country: Number of subjects enrolled | Netherlands: 49 |
| Worldwide total number of subjects   | 49              |
| EEA total number of subjects         | 49              |

Notes:

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**Subjects enrolled per age group**

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|   |    |
|---|----|
| 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                       | 7  |
| 85 years and over                         | 0  |

## Subject disposition

### Recruitment

Recruitment details:

Patients were assessed for eligibility during the preoperative screening visit. Patients were informed about the study verbally and in writing and written informed consent was obtained from all patients.

### Pre-assignment

Screening details:

Eligible patients were adults aged 18 or over with ASA physical health classification I–III, scheduled for single-injection ABPB for hand, wrist or forearm surgery. Exclusion criteria were infection at the injection site, coagulopathy, known hypersensitivity to amide-type local anesthetics, and known history of peripheral neuropathy.

### Period 1

|                              |   |
|------------------------------|---|
| Period 1 title               | overall study (overall period)                |
| Is this the baseline period? | Yes   |
| Allocation method            | Randomised - controlled                       |
| Blinding used                | Double blind                                  |
| Roles blinded                | Subject, Investigator, Data analyst, Assessor |

Blinding implementation details:

The anesthetic nurse that prepared the study medication was allowed to disclose allocation to the anesthesiologist that performed the block procedure. Both patients and researcher were blinded for the volume and concentration of anesthetic solution used.

### Arms

|  |                                  |
|--|----------------------------------|
| Are arms mutually exclusive?           | Yes                              |
| <b>Arm title</b>                       | Group A: 20 mL mepivacaine 1.5 % |
| Arm description: -                     |                                  |
| Arm type                               | Active comparator                |
| Investigational medicinal product name | mepivacaine                      |
| Investigational medicinal product code |                                  |
| Other name                             |                                  |
| Pharmaceutical forms                   | Solution for injection           |
| Routes of administration               | Perineural use                   |

Dosage and administration details:

The patient was placed in the supine position with the head facing away from the arm to be blocked, the arm abducted and the elbow flexed in 90°. A 100-mm 22-gauge insulated short bevel needle (Stimuplex®; B. Braun, Melsungen, Germany) was inserted laterally in the axilla under ultrasound guidance. The musculocutaneous, median, ulnar and radial nerve were identified using ultrasound and the tip of the needle was brought in proximity of each individual nerve subsequently. The needle was connected to a nerve stimulator (Stimuplex® HNS 11; B. Braun) set to deliver 100 nC (0.1 ms, 1 mA) in order to facilitate identification of the individual nerves. The nerves were identified and blocked separately with one fourth of the study medication per nerve. Per patient one skin puncture was made, the needle was retracted subcutaneously and redirected under ultrasound guidance to approach the nerves individually.

|  |                                  |
|--|----------------------------------|
| <b>Arm title</b>                       | Group B: 30 mL mepivacaine 1.0 % |
| Arm description: -                     |                                  |
| Arm type                               | Active comparator                |
| Investigational medicinal product name | mepivacaine                      |
| Investigational medicinal product code |                                  |
| Other name                             |                                  |
| Pharmaceutical forms                   | Solution for injection           |
| Routes of administration               | Perineural use                   |

Dosage and administration details:

The patient was placed in the supine position with the head facing away from the arm to be blocked, the

arm abducted and the elbow flexed in 90°. A 100-mm 22-gauge insulated short bevel needle (Stimuplex®; B. Braun, Melsungen, Germany) was inserted laterally in the axilla under ultrasound guidance. The musculocutaneous, median, ulnar and radial nerve were identified using ultrasound and the tip of the needle was brought in proximity of each individual nerve subsequently. The needle was connected to a nerve stimulator (Stimuplex® HNS 11; B. Braun) set to deliver 100 nC (0.1 ms, 1 mA) in order to facilitate identification of the individual nerves. The nerves were identified and blocked separately with one fourth of the study medication per nerve. Per patient one skin puncture was made, the needle was retracted subcutaneously and redirected under ultrasound guidance to approach the nerves individually.

|  |                                  |
|--|----------------------------------|
| <b>Arm title</b>                       | Group C: 30 mL mepivacaine 1.5 % |
| Arm description: -                     |                                  |
| Arm type                               | Active comparator                |
| Investigational medicinal product name | mepivacaine                      |
| Investigational medicinal product code |                                  |
| Other name                             |                                  |
| Pharmaceutical forms                   | Solution for injection           |
| Routes of administration               | Perineural use                   |

**Dosage and administration details:**

The patient was placed in the supine position with the head facing away from the arm to be blocked, the arm abducted and the elbow flexed in 90°. A 100-mm 22-gauge insulated short bevel needle (Stimuplex®; B. Braun, Melsungen, Germany) was inserted laterally in the axilla under ultrasound guidance. The musculocutaneous, median, ulnar and radial nerve were identified using ultrasound and the tip of the needle was brought in proximity of each individual nerve subsequently. The needle was connected to a nerve stimulator (Stimuplex® HNS 11; B. Braun) set to deliver 100 nC (0.1 ms, 1 mA) in order to facilitate identification of the individual nerves. The nerves were identified and blocked separately with one fourth of the study medication per nerve. Per patient one skin puncture was made, the needle was retracted subcutaneously and redirected under ultrasound guidance to approach the nerves individually.

| <b>Number of subjects in period 1</b> | Group A: 20 mL mepivacaine 1.5 % | Group B: 30 mL mepivacaine 1.0 % | Group C: 30 mL mepivacaine 1.5 % |
|---------------------------------------|----------------------------------|----------------------------------|----------------------------------|
| Started                               | 16                               | 18                               | 15                               |
| Completed                             | 15                               | 15                               | 15                               |
| Not completed                         | 1                                | 3                                | 0                                |
| Consent withdrawn by subject          | 1                                | -                                | -                                |
| block failure                         | -                                | 3                                | -                                |

## Baseline characteristics

### Reporting groups

|                       |               |
|-----------------------|---------------|
| Reporting group title | overall study |
|-----------------------|---------------|

Reporting group description: -

| Reporting group values                                | overall study | Total |  |
|---|---------------|-------|--|
| Number of subjects                                    | 49            | 49    |  |
| Age categorical                                       |               |       |  |
| Units: Subjects                                       |               |       |  |
| In utero  | 0             | 0     |  |
| Preterm newborn infants<br>(gestational age < 37 wks) | 0             | 0     |  |
| Newborns (0-27 days)                                  | 0             | 0     |  |
| Infants and toddlers (28 days-23<br>months)           | 0             | 0     |  |
| Children (2-11 years)                                 | 0             | 0     |  |
| Adolescents (12-17 years)                             | 0             | 0     |  |
| Adults (18-64 years)                                  | 42            | 42    |  |
| From 65-84 years                                      | 7             | 7     |  |
| 85 years and over                                     | 0             | 0     |  |
| Gender categorical                                    |               |       |  |
| Units: Subjects                                       |               |       |  |
| Female  | 34            | 34    |  |
| Male  | 15            | 15    |  |

## End points

### End points reporting groups

|                                |                                  |
|--------------------------------|----------------------------------|
| Reporting group title          | Group A: 20 mL mepivacaine 1.5 % |
| Reporting group description: - |                                  |
| Reporting group title          | Group B: 30 mL mepivacaine 1.0 % |
| Reporting group description: - |                                  |
| Reporting group title          | Group C: 30 mL mepivacaine 1.5 % |
| Reporting group description: - |                                  |

### Primary: duration of axillary plexus nerve block

|                        |   |
|------------------------|---|
| End point title        | duration of axillary plexus nerve block |
| End point description: |   |
| End point type         | Primary                                 |
| End point timeframe:   |   |
| total duration         |   |

| End point values                          | Group A: 20 mL mepivacaine 1.5 % | Group B: 30 mL mepivacaine 1.0 % | Group C: 30 mL mepivacaine 1.5 % |  |
|---|----------------------------------|----------------------------------|----------------------------------|--|
| Subject group type                        | Reporting group                  | Reporting group                  | Reporting group                  |  |
| Number of subjects analysed               | 15                               | 15                               | 15                               |  |
| Units: minutes                            |                                  |                                  |                                  |  |
| arithmetic mean (confidence interval 95%) |                                  |                                  |                                  |  |
| overall sensory                           | 256 (230 to 282)                 | 226 (209 to 243)                 | 270 (248 to 291)                 |  |
| overall motor                             | 254 (226 to 282)                 | 220 (200 to 240)                 | 264 (244 to 284)                 |  |

### Statistical analyses

|   |  |
|---|--|
| Statistical analysis title              | one-way ANOVA was used and Tukey post-hoc analyses   |
| Comparison groups                       | Group A: 20 mL mepivacaine 1.5 % v Group B: 30 mL mepivacaine 1.0 % v Group C: 30 mL mepivacaine 1.5 % |
| Number of subjects included in analysis | 45   |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | superiority  |
| P-value                                 | ≤ 0.05   |
| Method                                  | ANOVA  |

## Adverse events

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### Adverse events information<sup>[1]</sup>

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Timeframe for reporting adverse events:

for each subject the study duration is defined from the start of the block placement until the return of full motor and sensory skills of all nerves.

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

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### Dictionary used

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|                 |      |
|-----------------|------|
| Dictionary name | none |
|-----------------|------|

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|                    |   |
|--------------------|---|
| Dictionary version | 0 |
|--------------------|---|

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

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#### 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: this relatively short duration of the study and the small number of study participants is probably the reason that no SAE's took place

## 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

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

|  |
|--|
| Three patients were excluded because of block failure, all in Group B. Our study was not set up nor powered to assess success rate of the different concentrations. From a clinical perspective, 1 % mepivacaine may not be a suitable choice for ABPB |
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Notes:

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### Online references

<http://www.ncbi.nlm.nih.gov/pubmed/26423050>