



## Clinical trial results: DEXAMETHASONE AS ADJUVANT FOR PERIPHERAL NERVE BLOCKADE: A RANDOMIZED, TRIPLE-BLINDED AND CROSSOVER STUDY IN VOLUNTEERS

### Summary

|                          |                 |
|--------------------------|-----------------|
| EudraCT number           | 2018-001221-98  |
| Trial protocol           | AT              |
| Global end of trial date | 16 October 2018 |

### Results information

|                                |                   |
|--------------------------------|-------------------|
| Result version number          | v1 (current)      |
| This version publication date  | 21 September 2019 |
| First version publication date | 21 September 2019 |

### Trial information

#### Trial identification

|                       |     |
|-----------------------|-----|
| Sponsor protocol code | 1.3 |
|-----------------------|-----|

#### Additional study identifiers

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

Notes:

### Sponsors

|                              |   |
|------------------------------|---|
| Sponsor organisation name    | Medical University of Vienna  |
| Sponsor organisation address | Spitalgasse 23, Vienna, Austria, 1090   |
| Public contact               | Daniela Marhofer, Medical University of Vienna, Department of Anaesthesia, Intensive Care and Pain Medicine, +43 14040041030, daniela.marhofer@meduniwien.ac.at |
| Scientific contact           | Daniela Marhofer, Medical University of Vienna, Department of Anaesthesia, Intensive Care and Pain Medicine, +43 14040041030, daniela.marhofer@meduniwien.ac.at |

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                       | 16 November 2018 |
| Is this the analysis of the primary completion data? | Yes              |
| Primary completion date                              | 16 October 2018  |
| Global end of trial reached?                         | Yes              |
| Global end of trial date                             | 16 October 2018  |
| Was the trial ended prematurely?                     | No               |

Notes:

---

**General information about the trial**

---

Main objective of the trial:

To evaluate the impact of perineural dexamethasone on duration of sensory nerve blockade with clinical testing

Protection of trial subjects:

Subjects were during the trial under the supervision of a physician or an experienced nurse.

Background therapy: -

Evidence for comparator: -

|   |              |
|---|--------------|
| Actual start date of recruitment                          | 04 June 2018 |
| 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 | Austria: 24 |
| Worldwide total number of subjects   | 24          |
| EEA total number of subjects         | 24          |

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)                      | 24 |
| From 65 to 84 years                       | 0  |
| 85 years and over                         | 0  |

## Subject disposition

### Recruitment

Recruitment details:

Subjects were recruited by use of the data base of the Dep. of Clinical Pharmacology, Medical University of Vienna.

### Pre-assignment

Screening details:

Check of the in- and exclusion criteria, physical examination, vital signs, laboratory assessment and ECG recording

### 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          |

### Arms

|                              |    |
|------------------------------|----|
| Are arms mutually exclusive? | No |
|------------------------------|----|

|                  |               |
|------------------|---------------|
| <b>Arm title</b> | Study group 1 |
|------------------|---------------|

Arm description: -

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

Dosage and administration details:

Ropivacaine 0.75% / perineural Dexamethasone  
4mg (= 4ml Ropivacaine 0.56%) & Saline 1ml iv

|                  |               |
|------------------|---------------|
| <b>Arm title</b> | Study group 2 |
|------------------|---------------|

Arm description: -

|  |                                 |
|--|---------------------------------|
| Arm type                               | Experimental                    |
| Investigational medicinal product name | Dexamethasone                   |
| Investigational medicinal product code |                                 |
| Other name                             |                                 |
| Pharmaceutical forms                   | Solution for injection/infusion |
| Routes of administration               | Intravenous use                 |

Dosage and administration details:

4ml Ropivacaine 0.56% & Dexamethasone 4mg iv

|                  |               |
|------------------|---------------|
| <b>Arm title</b> | Study group 3 |
|------------------|---------------|

Arm description: -

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

Dosage and administration details:

4ml Ropivacaine 0.56% & Saline 1ml iv

| <b>Number of subjects in period 1</b> | Study group 1 | Study group 2 | Study group 3 |
|---------------------------------------|---------------|---------------|---------------|
| Started                               | 24            | 24            | 24            |
| Completed                             | 24            | 24            | 24            |

## Baseline characteristics

### Reporting groups

Reporting group title

Overall trial

Reporting group description: -

| Reporting group values                                | Overall trial | Total |  |
|---|---------------|-------|--|
| Number of subjects                                    | 24            | 24    |  |
| 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)                                  | 24            | 24    |  |
| From 65-84 years                                      | 0             | 0     |  |
| 85 years and over                                     | 0             | 0     |  |
| Gender categorical                                    |               |       |  |
| Units: Subjects                                       |               |       |  |
| Female  | 0             | 0     |  |
| Male  | 24            | 24    |  |

## End points

### End points reporting groups

|                                |               |
|--------------------------------|---------------|
| Reporting group title          | Study group 1 |
| Reporting group description: - |               |
| Reporting group title          | Study group 2 |
| Reporting group description: - |               |
| Reporting group title          | Study group 3 |
| Reporting group description: - |               |

### Primary: To evaluate the impact of perineural dexamethasone on duration of sensory nerve blockade with clinical testing

|                        |  |
|------------------------|--|
| End point title        | To evaluate the impact of perineural dexamethasone on duration of sensory nerve blockade with clinical testing |
| End point description: |  |
| End point type         | Primary  |
| End point timeframe:   | Baseline, 2, 4, 6, 8, 10, 15, 20, 30, 60 min after the block, and then every 30 min until complete recovery.   |

| End point values            | Study group 1   | Study group 2   | Study group 3   |  |
|-----------------------------|-----------------|-----------------|-----------------|--|
| Subject group type          | Reporting group | Reporting group | Reporting group |  |
| Number of subjects analysed | 24              | 24              | 24              |  |
| Units: time/ minutes        |                 |                 |                 |  |
| number (not applicable)     | 24              | 24              | 24              |  |

### Statistical analyses

|   |   |
|---|---|
| Statistical analysis title              | Statistics to end point                       |
| Comparison groups                       | Study group 1 v Study group 2 v Study group 3 |
| Number of subjects included in analysis | 72  |
| Analysis specification                  | Pre-specified                                 |
| Analysis type                           | other   |
| P-value                                 | = 0.05  |
| Method                                  | t-test, 2-sided                               |

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

22.06.2018-16.10.2018

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

### Dictionary used

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

|                    |      |
|--------------------|------|
| Dictionary version | 22.0 |
|--------------------|------|

### Reporting groups

|                       |               |
|-----------------------|---------------|
| Reporting group title | Overall trial |
|-----------------------|---------------|

Reporting group description: -

| Serious adverse events                            | Overall trial  |  |  |
|---|----------------|--|--|
| Total subjects affected by serious adverse events |                |  |  |
| subjects affected / exposed                       | 0 / 24 (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                            | Overall trial   |  |  |
|---|-----------------|--|--|
| Total subjects affected by non-serious adverse events |                 |  |  |
| subjects affected / exposed                           | 3 / 24 (12.50%) |  |  |
| Nervous system disorders                              |                 |  |  |
| Dizziness   |                 |  |  |
| subjects affected / exposed                           | 1 / 24 (4.17%)  |  |  |
| occurrences (all)                                     | 1               |  |  |
| General disorders and administration site conditions  |                 |  |  |
| Sickness  |                 |  |  |
| subjects affected / exposed                           | 1 / 24 (4.17%)  |  |  |
| occurrences (all)                                     | 1               |  |  |
| Pain  |                 |  |  |
| subjects affected / exposed                           | 1 / 24 (4.17%)  |  |  |
| occurrences (all)                                     | 1               |  |  |
| Eye disorders   |                 |  |  |

|  |                     |  |  |
|--|---------------------|--|--|
| Erosio corneae<br>subjects affected / exposed<br>occurrences (all)                             | 1 / 24 (4.17%)<br>1 |  |  |
| Gastrointestinal disorders<br>Soft stool<br>subjects affected / exposed<br>occurrences (all)   | 1 / 24 (4.17%)<br>1 |  |  |
| Infections and infestations<br>Common cold<br>subjects affected / exposed<br>occurrences (all) | 1 / 24 (4.17%)<br>1 |  |  |



## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date           | Amendment                           |
|----------------|-------------------------------------|
| 07 August 2018 | Change in patient information sheet |

Notes:

---

### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported