



## Clinical trial results:

### Postoperative analgesia after elective hip surgery - effect of obturator nerve blockade

#### Summary

|                          |                |
|--------------------------|----------------|
| EudraCT number           | 2017-000068-14 |
| Trial protocol           | DK             |
| Global end of trial date | 08 June 2018   |

#### Results information

|                                |                  |
|--------------------------------|------------------|
| Result version number          | v1 (current)     |
| This version publication date  | 27 November 2019 |
| First version publication date | 27 November 2019 |

#### Trial information

##### Trial identification

|                       |              |
|-----------------------|--------------|
| Sponsor protocol code | HIP/FUSION#2 |
|-----------------------|--------------|

##### Additional study identifiers

|                                    |             |
|------------------------------------|-------------|
| ISRCTN number                      | -           |
| ClinicalTrials.gov id (NCT number) | NCT03064165 |
| WHO universal trial number (UTN)   | -           |

Notes:

##### Sponsors

|                              |  |
|------------------------------|--|
| Sponsor organisation name    | Thomas Fichtner Bendtsen   |
| Sponsor organisation address | Palle Juul-Jensens Boulevard 165, Aarhus N, Denmark,                               |
| Public contact               | Niels Dalsgaard Nielsen, Elective Surgery Center, +45 22838334, nielsdn@dadlnet.dk |
| Scientific contact           | Niels Dalsgaard Nielsen, Elective Surgery Center, +45 22838334, nielsdn@dadlnet.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:

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**Results analysis stage**

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|  |              |
|--|--------------|
| Analysis stage                                       | Final        |
| Date of interim/final analysis                       | 14 June 2018 |
| Is this the analysis of the primary completion data? | Yes          |
| Primary completion date                              | 08 June 2018 |
| Global end of trial reached?                         | Yes          |
| Global end of trial date                             | 08 June 2018 |
| 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:

To estimate the effect of obturator nerve blockade on postoperative opioid consumption 0-12 hours after total hip replacement.

Protection of trial subjects:

No specific measures was observed.

Background therapy: -

Evidence for comparator: -

|   |             |
|---|-------------|
| Actual start date of recruitment                          | 01 May 2017 |
| Long term follow-up planned                               | No          |
| Independent data monitoring committee (IDMC) involvement? | Yes         |

Notes:

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**Population of trial subjects**

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**Subjects enrolled per country**

|                                      |             |
|--------------------------------------|-------------|
| Country: Number of subjects enrolled | Denmark: 62 |
| Worldwide total number of subjects   | 62          |
| EEA total number of subjects         | 62          |

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)                      | 17 |
| From 65 to 84 years                       | 41 |
| 85 years and over                         | 4  |

## Subject disposition

### Recruitment

Recruitment details:

We included patients aged  $\geq 18$  years with ASA I–III status who were scheduled for primary THA in spinal anesthesia at the Elective Surgery Center, Silkeborg Regional Hospital, Silkeborg, Denmark.

### Pre-assignment

Screening details:

Assessed for eligibility, n=284; Excluded, n=222, cause of exclusion: Meeting exclusion criteria, n=154, Declined to participate, n=33, Other reasons, n=35; Randomized, n=62, thereof: Completing trial, n=60, Excluded after inclusion, n=2.

### 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                |
| <b>Arm title</b>             | Active nerve block |

Arm description:

Subjects received an active obturator nerve block within 1 hour after total hip arthroplasty.

|  |   |
|--|---|
| Arm type                               | Experimental                                      |
| Investigational medicinal product name | Bupivacaine 5 mg/mL with epinephrine 5 $\mu$ g/mL |
| Investigational medicinal product code |   |
| Other name                             |   |
| Pharmaceutical forms                   | Injection   |
| Routes of administration               | Perineural use                                    |

Dosage and administration details:

Single injection of 15 mL bupivacaine 5 mg/mL with epinephrine 5  $\mu$ g/mL in the interfascial plane between the pectineus and external obturator muscles.

|                  |                  |
|------------------|------------------|
| <b>Arm title</b> | Sham nerve block |
|------------------|------------------|

Arm description:

Subjects received a sham obturator nerve block (placebo) within 1 hour after total hip arthroplasty.

|  |                |
|--|----------------|
| Arm type                               | Placebo        |
| Investigational medicinal product name | Normal saline  |
| Investigational medicinal product code |                |
| Other name                             |                |
| Pharmaceutical forms                   | Injection      |
| Routes of administration               | Perineural use |

Dosage and administration details:

Single injection of 15 mL bupivacaine 5 mg/mL with epinephrine 5  $\mu$ g/mL in the interfascial plane between the pectineus and external obturator muscles.

| <b>Number of subjects in period 1</b> | Active nerve block | Sham nerve block |
|---------------------------------------|--------------------|------------------|
| Started                               | 31                 | 31               |
| Completed                             | 30                 | 30               |
| Not completed                         | 1                  | 1                |
| Protocol deviation                    | 1                  | 1                |

## Baseline characteristics

## End points

### End points reporting groups

|  |                    |
|--|--------------------|
| Reporting group title  | Active nerve block |
| Reporting group description:<br>Subjects received an active obturator nerve block within 1 hour after total hip arthroplasty.        |                    |
| Reporting group title  | Sham nerve block   |
| Reporting group description:<br>Subjects received a sham obturator nerve block (placebo) within 1 hour after total hip arthroplasty. |                    |

### Primary: Cumulated opioid dose (0-12 h)

|   |                                |
|---|--------------------------------|
| End point title   | Cumulated opioid dose (0-12 h) |
| End point description:<br>Opioid consumption was converted to Oram morphine equivalents |                                |
| End point type  | Primary                        |
| End point timeframe:<br>0-12 hours after surgery  |                                |

| End point values                     | Active nerve block | Sham nerve block   |  |  |
|--------------------------------------|--------------------|--------------------|--|--|
| Subject group type                   | Reporting group    | Reporting group    |  |  |
| Number of subjects analysed          | 30                 | 30                 |  |  |
| Units: milligram(s)                  |                    |                    |  |  |
| arithmetic mean (standard deviation) | 39.9 ( $\pm$ 22.3) | 40.5 ( $\pm$ 30.5) |  |  |

### Statistical analyses

|   |                                       |
|---|---------------------------------------|
| Statistical analysis title              | Student t-test                        |
| Comparison groups                       | Sham nerve block v Active nerve block |
| Number of subjects included in analysis | 60                                    |
| Analysis specification                  | Pre-specified                         |
| Analysis type                           | equivalence                           |
| P-value                                 | = 0.93                                |
| Method                                  | t-test, 2-sided                       |
| Parameter estimate                      | Mean difference (final values)        |
| Point estimate                          | 0.6                                   |
| Confidence interval                     |                                       |
| level                                   | 95 %                                  |
| sides                                   | 2-sided                               |
| lower limit                             | -14                                   |
| upper limit                             | 13                                    |
| Variability estimate                    | Standard error of the mean            |
| Dispersion value                        | 6.9                                   |

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**Secondary: Cumulated opioid dose (12-18 h)**

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|                 |                                 |
|-----------------|---------------------------------|
| End point title | Cumulated opioid dose (12-18 h) |
|-----------------|---------------------------------|

End point description:

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

End point timeframe:

12–18 hours after surgery

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| End point values                      | Active nerve block | Sham nerve block |  |  |
|---------------------------------------|--------------------|------------------|--|--|
| Subject group type                    | Reporting group    | Reporting group  |  |  |
| Number of subjects analysed           | 30                 | 30               |  |  |
| Units: milligram(s)                   |                    |                  |  |  |
| median (inter-quartile range (Q1-Q3)) | 12.5 (0 to 17.0)   | 10.1 (0 to 17.3) |  |  |

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**Statistical analyses**

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No statistical analyses for this end point

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**Secondary: Pain score at rest (1 h)**

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|                 |                          |
|-----------------|--------------------------|
| End point title | Pain score at rest (1 h) |
|-----------------|--------------------------|

End point description:

Pain evaluated by subject on numeric rating score from 0 (no pain) to 10 (worst pain imaginable)

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

End point timeframe:

1 hour after end-of-surgery

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| End point values                      | Active nerve block | Sham nerve block |  |  |
|---------------------------------------|--------------------|------------------|--|--|
| Subject group type                    | Reporting group    | Reporting group  |  |  |
| Number of subjects analysed           | 30                 | 30               |  |  |
| Units: Numeric Rating Score           |                    |                  |  |  |
| median (inter-quartile range (Q1-Q3)) | 0 (0 to 0)         | 0 (0 to 0)       |  |  |

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**Statistical analyses**

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No statistical analyses for this end point

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**Secondary: Pain score at rest (2 h)**

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|                 |                          |
|-----------------|--------------------------|
| End point title | Pain score at rest (2 h) |
|-----------------|--------------------------|

End point description:

Pain evaluated by subject on numeric rating score from 0 (no pain) to 10 (worst pain imaginable)

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

End point timeframe:

2 hours after end-of-surgery

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| End point values                      | Active nerve block | Sham nerve block |  |  |
|---------------------------------------|--------------------|------------------|--|--|
| Subject group type                    | Reporting group    | Reporting group  |  |  |
| Number of subjects analysed           | 30                 | 30               |  |  |
| Units: Numeric Rating Scale           |                    |                  |  |  |
| median (inter-quartile range (Q1-Q3)) | 0 (0 to 2)         | 0 (0 to 2)       |  |  |

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**Statistical analyses**

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No statistical analyses for this end point

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**Secondary: Pain score at rest (5 h)**

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|                 |                          |
|-----------------|--------------------------|
| End point title | Pain score at rest (5 h) |
|-----------------|--------------------------|

End point description:

Pain evaluated by subject on numeric rating score from 0 (no pain) to 10 (worst pain imaginable)

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

End point timeframe:

5 hours after end-of-surgery.

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| End point values                      | Active nerve block | Sham nerve block |  |  |
|---------------------------------------|--------------------|------------------|--|--|
| Subject group type                    | Reporting group    | Reporting group  |  |  |
| Number of subjects analysed           | 30                 | 30               |  |  |
| Units: Numeric Rating Score           |                    |                  |  |  |
| median (inter-quartile range (Q1-Q3)) | 2 (1 to 3)         | 2.5 (2 to 3.25)  |  |  |

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**Statistical analyses**

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No statistical analyses for this end point

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**Secondary: Pain score at rest (7 h)**

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|                 |                          |
|-----------------|--------------------------|
| End point title | Pain score at rest (7 h) |
|-----------------|--------------------------|



|  |           |
|--|-----------|
| End point description:   |           |
| Pain evaluated by subject on numeric rating score from 0 (no pain) to 10 (worst pain imaginable) |           |
| End point type   | Secondary |
| End point timeframe:   |           |
| 7 hours after end-of-surgery.  |           |

| End point values                      | Active nerve block | Sham nerve block |  |  |
|---------------------------------------|--------------------|------------------|--|--|
| Subject group type                    | Reporting group    | Reporting group  |  |  |
| Number of subjects analysed           | 30                 | 30               |  |  |
| Units: Numeric Rating Score           |                    |                  |  |  |
| median (inter-quartile range (Q1-Q3)) | 2 (1 to 3)         | 2 (1 to 3)       |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Pain score at rest (24 h)

|                               |                           |
|-------------------------------|---------------------------|
| End point title               | Pain score at rest (24 h) |
| End point description:        |                           |
| End point type                |                           |
| Secondary                     |                           |
| End point timeframe:          |                           |
| 24 hours after end-of-surgery |                           |

| End point values                      | Active nerve block | Sham nerve block |  |  |
|---------------------------------------|--------------------|------------------|--|--|
| Subject group type                    | Reporting group    | Reporting group  |  |  |
| Number of subjects analysed           | 30                 | 30               |  |  |
| Units: Numeric Rating Score           |                    |                  |  |  |
| median (inter-quartile range (Q1-Q3)) | 1 (0 to 2)         | 1 (0 to 2)       |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Pain score during passive 90° flexion of the hip (1 h)

|  |  |
|--|--|
| End point title  | Pain score during passive 90° flexion of the hip (1 h) |
| End point description:   |  |
| Pain evaluated by subject on numeric rating score from 0 (no pain) to 10 (worst pain imaginable) |  |
| End point type   | Secondary  |

End point timeframe:

1 hour after end-of-surgery.

| End point values                      | Active nerve block | Sham nerve block |  |  |
|---------------------------------------|--------------------|------------------|--|--|
| Subject group type                    | Reporting group    | Reporting group  |  |  |
| Number of subjects analysed           | 30                 | 30               |  |  |
| Units: Numeric Rating Score           |                    |                  |  |  |
| median (inter-quartile range (Q1-Q3)) | 0 (0 to 0)         | 0 (0 to 0)       |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Pain score during passive 90° flexion of the hip (2 h)

|                        |  |
|------------------------|--|
| End point title        | Pain score during passive 90° flexion of the hip (2 h)   |
| End point description: | Pain evaluated by subject on numeric rating score from 0 (no pain) to 10 (worst pain imaginable) |
| End point type         | Secondary  |
| End point timeframe:   | 2 hours after end-of-surgery   |

| End point values                      | Active nerve block | Sham nerve block |  |  |
|---------------------------------------|--------------------|------------------|--|--|
| Subject group type                    | Reporting group    | Reporting group  |  |  |
| Number of subjects analysed           | 30                 | 30               |  |  |
| Units: Numeric Rating Score           |                    |                  |  |  |
| median (inter-quartile range (Q1-Q3)) | 0 (0 to 2)         | 0.5 (0 to 3)     |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Pain score during passive 90° flexion of the hip (5 h)

|                        |  |
|------------------------|--|
| End point title        | Pain score during passive 90° flexion of the hip (5 h)   |
| End point description: | Pain evaluated by subject on numeric rating score from 0 (no pain) to 10 (worst pain imaginable) |
| End point type         | Secondary  |
| End point timeframe:   | 5 hours after end-of-surgery   |

| End point values                      | Active nerve block | Sham nerve block |  |  |
|---------------------------------------|--------------------|------------------|--|--|
| Subject group type                    | Reporting group    | Reporting group  |  |  |
| Number of subjects analysed           | 30                 | 30               |  |  |
| Units: Numeric Rating Score           |                    |                  |  |  |
| median (inter-quartile range (Q1-Q3)) | 3.5 (1 to 5)       | 3 (2 to 5)       |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Pain score during passive 90° flexion of the hip (7 h)

|  |  |
|--|--|
| End point title  | Pain score during passive 90° flexion of the hip (7 h) |
| End point description:<br>Pain evaluated by subject on numeric rating score from 0 (no pain) to 10 (worst pain imaginable) |  |
| End point type   | Secondary  |
| End point timeframe:<br>5 hours after end-of-surgery   |  |

| End point values                      | Active nerve block | Sham nerve block |  |  |
|---------------------------------------|--------------------|------------------|--|--|
| Subject group type                    | Reporting group    | Reporting group  |  |  |
| Number of subjects analysed           | 30                 | 30               |  |  |
| Units: Numeric Rating Score           |                    |                  |  |  |
| median (inter-quartile range (Q1-Q3)) | 4 (2.5 to 5)       | 3 (2 to 6)       |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Pain score during passive 90° flexion of the hip (24 h)

|  |   |
|--|---|
| End point title  | Pain score during passive 90° flexion of the hip (24 h) |
| End point description:<br>Pain evaluated by subject on numeric rating score from 0 (no pain) to 10 (worst pain imaginable) |   |
| End point type   | Secondary   |
| End point timeframe:<br>24 hours after end-of-surgery  |   |

| End point values                      | Active nerve block | Sham nerve block |  |  |
|---------------------------------------|--------------------|------------------|--|--|
| Subject group type                    | Reporting group    | Reporting group  |  |  |
| Number of subjects analysed           | 30                 | 30               |  |  |
| Units: Numeric Rating Score           |                    |                  |  |  |
| median (inter-quartile range (Q1-Q3)) | 3 (2 to 4)         | 3 (1 to 5.25)    |  |  |

### Statistical analyses

No statistical analyses for this end point

#### Secondary: Intensity of nausea (1 h)

|  |                           |
|--|---------------------------|
| End point title  | Intensity of nausea (1 h) |
| End point description:<br>Nausea evaluated by subject on numeric rating score from 0 (no nausea) to 10 (worst nausea imaginable) |                           |
| End point type   | Secondary                 |
| End point timeframe:<br>1 hour after end-of-surgery  |                           |

| End point values                      | Active nerve block | Sham nerve block |  |  |
|---------------------------------------|--------------------|------------------|--|--|
| Subject group type                    | Reporting group    | Reporting group  |  |  |
| Number of subjects analysed           | 30                 | 30               |  |  |
| Units: Numeric Rating Score           |                    |                  |  |  |
| median (inter-quartile range (Q1-Q3)) | 0 (0 to 0)         | 0 (0 to 0)       |  |  |

### Statistical analyses

No statistical analyses for this end point

#### Secondary: Intensity of nausea (2 h)

|  |                           |
|--|---------------------------|
| End point title  | Intensity of nausea (2 h) |
| End point description:<br>Nausea evaluated by subject on numeric rating score from 0 (no nausea) to 10 (worst nausea imaginable) |                           |
| End point type   | Secondary                 |
| End point timeframe:<br>2 hours after end-of-surgery   |                           |

| End point values                      | Active nerve block | Sham nerve block |  |  |
|---------------------------------------|--------------------|------------------|--|--|
| Subject group type                    | Reporting group    | Reporting group  |  |  |
| Number of subjects analysed           | 30                 | 30               |  |  |
| Units: Numeric Rating Score           |                    |                  |  |  |
| median (inter-quartile range (Q1-Q3)) | 0 (0 to 0)         | 0 (0 to 0)       |  |  |

### Statistical analyses

No statistical analyses for this end point

#### Secondary: Intensity of nausea (5 h)

|  |                           |
|--|---------------------------|
| End point title  | Intensity of nausea (5 h) |
| End point description:<br>Nausea evaluated by subject on numeric rating score from 0 (no nausea) to 10 (worst nausea imaginable) |                           |
| End point type   | Secondary                 |
| End point timeframe:<br>5 hours after end-of-surgery   |                           |

| End point values                      | Active nerve block | Sham nerve block |  |  |
|---------------------------------------|--------------------|------------------|--|--|
| Subject group type                    | Reporting group    | Reporting group  |  |  |
| Number of subjects analysed           | 30                 | 30               |  |  |
| Units: Numeric Rating Score           |                    |                  |  |  |
| median (inter-quartile range (Q1-Q3)) | 0 (0 to 0)         | 0 (0 to 0)       |  |  |

### Statistical analyses

No statistical analyses for this end point

#### Secondary: Intensity of nausea (7 h)

|  |                           |
|--|---------------------------|
| End point title  | Intensity of nausea (7 h) |
| End point description:<br>Nausea evaluated by subject on numeric rating score from 0 (no nausea) to 10 (worst nausea imaginable) |                           |
| End point type   | Secondary                 |
| End point timeframe:<br>7 hours after end-of-surgery   |                           |

| End point values                      | Active nerve block | Sham nerve block |  |  |
|---------------------------------------|--------------------|------------------|--|--|
| Subject group type                    | Reporting group    | Reporting group  |  |  |
| Number of subjects analysed           | 30                 | 30               |  |  |
| Units: Numeric Rating Score           |                    |                  |  |  |
| median (inter-quartile range (Q1-Q3)) | 0 (0 to 0)         | 0 (0 to 0)       |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Intensity of nausea (24 h)

|  |                            |
|--|----------------------------|
| End point title  | Intensity of nausea (24 h) |
| End point description:<br>Nausea evaluated by subject on numeric rating score from 0 (no nausea) to 10 (worst nausea imaginable) |                            |
| End point type   | Secondary                  |
| End point timeframe:<br>24 hours after end-of-surgery  |                            |

| End point values                      | Active nerve block | Sham nerve block |  |  |
|---------------------------------------|--------------------|------------------|--|--|
| Subject group type                    | Reporting group    | Reporting group  |  |  |
| Number of subjects analysed           | 30                 | 30               |  |  |
| Units: Numeric Rating Score           |                    |                  |  |  |
| median (inter-quartile range (Q1-Q3)) | 0 (0 to 0)         | 0 (0 to 0)       |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of episodes of emesis (0-18 h)

|  |                                       |
|--|---------------------------------------|
| End point title  | Number of episodes of emesis (0-18 h) |
| End point description:                                     |                                       |
| End point type   | Secondary                             |
| End point timeframe:<br>0 to 18 hours after end-of surgery |                                       |

| End point values                      | Active nerve block | Sham nerve block |  |  |
|---------------------------------------|--------------------|------------------|--|--|
| Subject group type                    | Reporting group    | Reporting group  |  |  |
| Number of subjects analysed           | 30                 | 30               |  |  |
| Units: Number of episodes             |                    |                  |  |  |
| median (inter-quartile range (Q1-Q3)) | 0 (0 to 0)         | 0 (0 to 0)       |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Cumulated dose of ondansetron (0-18 h)

|                                    |  |
|------------------------------------|--|
| End point title                    | Cumulated dose of ondansetron (0-18 h) |
| End point description:             |  |
| End point type                     | Secondary                              |
| End point timeframe:               |  |
| 0 to 18 hours after end-of-surgery |  |

| End point values                      | Active nerve block | Sham nerve block |  |  |
|---------------------------------------|--------------------|------------------|--|--|
| Subject group type                    | Reporting group    | Reporting group  |  |  |
| Number of subjects analysed           | 30                 | 30               |  |  |
| Units: milligram(s)                   |                    |                  |  |  |
| median (inter-quartile range (Q1-Q3)) | 0 (0 to 0)         | 0 (0 to 0)       |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Cumulated dose of droperidol (0-18 h)

|                                    |                                       |
|------------------------------------|---------------------------------------|
| End point title                    | Cumulated dose of droperidol (0-18 h) |
| End point description:             |                                       |
| End point type                     | Secondary                             |
| End point timeframe:               |                                       |
| 0 to 18 hours after end-of-surgery |                                       |

| End point values                      | Active nerve block | Sham nerve block |  |  |
|---------------------------------------|--------------------|------------------|--|--|
| Subject group type                    | Reporting group    | Reporting group  |  |  |
| Number of subjects analysed           | 30                 | 30               |  |  |
| Units: milligram(s)                   |                    |                  |  |  |
| median (inter-quartile range (Q1-Q3)) | 0 (0 to 0)         | 0 (0 to 0)       |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Time to discharge from the postanesthesia care unit (PACU)

|                 |  |
|-----------------|--|
| End point title | Time to discharge from the postanesthesia care unit (PACU) |
|-----------------|--|

End point description:

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

End point timeframe:

From end-of-surgery until discharge from PACU.

| End point values                     | Active nerve block | Sham nerve block |  |  |
|--------------------------------------|--------------------|------------------|--|--|
| Subject group type                   | Reporting group    | Reporting group  |  |  |
| Number of subjects analysed          | 30                 | 30               |  |  |
| Units: minute                        |                    |                  |  |  |
| arithmetic mean (standard deviation) | 106 ( $\pm$ 38)    | 123 ( $\pm$ 49)  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Time to discharge from the hospital

|                 |                                     |
|-----------------|-------------------------------------|
| End point title | Time to discharge from the hospital |
|-----------------|-------------------------------------|

End point description:

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

End point timeframe:

Time from end-of-surgery to discharge from hospital.



| End point values                      | Active nerve block | Sham nerve block |  |  |
|---------------------------------------|--------------------|------------------|--|--|
| Subject group type                    | Reporting group    | Reporting group  |  |  |
| Number of subjects analysed           | 30                 | 30               |  |  |
| Units: hour                           |                    |                  |  |  |
| median (inter-quartile range (Q1-Q3)) | 28 (26 to 29)      | 28 (26 to 29)    |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Duration of the spinal anesthesia

|   |                                   |
|---|-----------------------------------|
| End point title   | Duration of the spinal anesthesia |
| End point description:  |                                   |
|   |                                   |
| End point type  | Secondary                         |
| End point timeframe:  |                                   |
| Time from end-of-surgery until subject regains normal sensibility on anterior surface of femur. |                                   |

| End point values                     | Active nerve block | Sham nerve block |  |  |
|--------------------------------------|--------------------|------------------|--|--|
| Subject group type                   | Reporting group    | Reporting group  |  |  |
| Number of subjects analysed          | 30                 | 30               |  |  |
| Units: minute                        |                    |                  |  |  |
| arithmetic mean (standard deviation) | 152 ( $\pm$ 38)    | 167 ( $\pm$ 44)  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Quality of sleep

|   |                  |
|---|------------------|
| End point title                                       | Quality of sleep |
| End point description:                                |                  |
| Quality of sleep during the first night after surgery |                  |
| End point type  | Secondary        |
| End point timeframe:                                  |                  |
| 24 hours  |                  |

| End point values                | Active nerve block | Sham nerve block |  |  |
|---------------------------------|--------------------|------------------|--|--|
| Subject group type              | Reporting group    | Reporting group  |  |  |
| Number of subjects analysed     | 30                 | 30               |  |  |
| Units: Categorical (see below)  |                    |                  |  |  |
| Sleep undisturbed               | 6                  | 5                |  |  |
| Sleep disturbed but not by pain | 21                 | 18               |  |  |
| Sleep disturbed by pain         | 3                  | 7                |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Ability to ambulate (5 h)

|  |                           |
|--|---------------------------|
| End point title  | Ability to ambulate (5 h) |
| End point description:<br>The ability to ambulate was assessed by physiotherapists using a standardized ambulation test ranging from 0 (subject was unable to ambulate to sitting position) to 8 (subject could walk with elbow crutches without personal physical support). |                           |
| End point type   | Secondary                 |
| End point timeframe:<br>5 hours after end-of-surgery   |                           |

| End point values                      | Active nerve block | Sham nerve block |  |  |
|---------------------------------------|--------------------|------------------|--|--|
| Subject group type                    | Reporting group    | Reporting group  |  |  |
| Number of subjects analysed           | 30                 | 30               |  |  |
| Units: Numeric Rating Score           |                    |                  |  |  |
| median (inter-quartile range (Q1-Q3)) | 6 (4.5 to 8)       | 7 (6 to 8)       |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Muscular control of the operated leg during ambulation (5 h)

|   |  |
|---|--|
| End point title   | Muscular control of the operated leg during ambulation (5 h) |
| End point description:<br>The range of the muscular control score was 0 (subject was unable to ambulate to sitting position) to 3 (subject had good muscular control of the operated leg during all activities) |  |
| End point type  | Secondary  |
| End point timeframe:<br>5 hours after end-of-surgery.   |  |

| <b>End point values</b>               | Active nerve block | Sham nerve block |  |  |
|---------------------------------------|--------------------|------------------|--|--|
| Subject group type                    | Reporting group    | Reporting group  |  |  |
| Number of subjects analysed           | 30                 | 30               |  |  |
| Units: Numeric Rating Score           |                    |                  |  |  |
| median (inter-quartile range (Q1-Q3)) | 2.5 (2 to 3)       | 3 (2.5 to 3)     |  |  |

### Statistical analyses

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No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

24 hours after end-of-surgery

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

### Dictionary used

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

|                    |    |
|--------------------|----|
| Dictionary version | 21 |
|--------------------|----|

### Reporting groups

|                       |                    |
|-----------------------|--------------------|
| Reporting group title | Active nerve block |
|-----------------------|--------------------|

Reporting group description:

Subjects received an active obturator nerve block within 1 hour after total hip arthroplasty.

|                       |                  |
|-----------------------|------------------|
| Reporting group title | Sham nerve block |
|-----------------------|------------------|

Reporting group description:

Subjects received a sham obturator nerve block (placebo) within 1 hour after total hip arthroplasty.

| Serious adverse events                            | Active nerve block | Sham nerve block |  |
|---|--------------------|------------------|--|
| Total subjects affected by serious adverse events |                    |                  |  |
| subjects affected / exposed                       | 0 / 31 (0.00%)     | 0 / 31 (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                            | Active nerve block | Sham nerve block |  |
|---|--------------------|------------------|--|
| Total subjects affected by non-serious adverse events |                    |                  |  |
| subjects affected / exposed                           | 10 / 31 (32.26%)   | 10 / 31 (32.26%) |  |
| Nervous system disorders                              |                    |                  |  |
| Decreased consciousness                               |                    |                  |  |
| alternative assessment type: Non-systematic           |                    |                  |  |
| subjects affected / exposed                           | 0 / 31 (0.00%)     | 1 / 31 (3.23%)   |  |
| occurrences (all)                                     | 0                  | 1                |  |
| Vertigo / indisposition                               |                    |                  |  |
| subjects affected / exposed                           | 3 / 31 (9.68%)     | 2 / 31 (6.45%)   |  |
| occurrences (all)                                     | 3                  | 2                |  |
| Fainting  |                    |                  |  |

|                                      |                 |                 |  |
|--------------------------------------|-----------------|-----------------|--|
| subjects affected / exposed          | 1 / 31 (3.23%)  | 0 / 31 (0.00%)  |  |
| occurrences (all)                    | 0               | 0               |  |
| Confusion postoperative              |                 |                 |  |
| subjects affected / exposed          | 0 / 31 (0.00%)  | 1 / 31 (3.23%)  |  |
| occurrences (all)                    | 0               | 0               |  |
| Blood and lymphatic system disorders |                 |                 |  |
| Seepage from surgical wound          |                 |                 |  |
| subjects affected / exposed          | 4 / 31 (12.90%) | 2 / 31 (6.45%)  |  |
| occurrences (all)                    | 4               | 2               |  |
| Arterial hypotension                 |                 |                 |  |
| subjects affected / exposed          | 0 / 31 (0.00%)  | 2 / 31 (6.45%)  |  |
| occurrences (all)                    | 0               | 0               |  |
| Gastrointestinal disorders           |                 |                 |  |
| Nausea and/or vomiting               |                 |                 |  |
| subjects affected / exposed          | 2 / 31 (6.45%)  | 4 / 31 (12.90%) |  |
| occurrences (all)                    | 2               | 4               |  |
| Renal and urinary disorders          |                 |                 |  |
| Urinary retention                    |                 |                 |  |
| subjects affected / exposed          | 1 / 31 (3.23%)  | 0 / 31 (0.00%)  |  |
| occurrences (all)                    | 1               | 0               |  |
| Acute-in-chronic renal failure       |                 |                 |  |
| subjects affected / exposed          | 0 / 31 (0.00%)  | 1 / 31 (3.23%)  |  |
| occurrences (all)                    | 0               | 1               |  |
| Endocrine disorders                  |                 |                 |  |
| Anafylactoid reaction                |                 |                 |  |
| subjects affected / exposed          | 1 / 31 (3.23%)  | 0 / 31 (0.00%)  |  |
| occurrences (all)                    | 1               | 0               |  |

## 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

None reported

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### Online references

<http://www.ncbi.nlm.nih.gov/pubmed/31650529>