



Clinical trial results:

Transversus abdominis plane blok, continuous systemic administration of lidocaine and patient controlled intravenous morphine - 3 methods for postoperative pain control after laparoscopic colorectal surgery: a randomised comparative trial.

Summary

| | |
|--------------------------|-----------------|
| EudraCT number | 2014-001499-73 |
| Trial protocol | BE |
| Global end of trial date | 16 January 2017 |

Results information

| | |
|--------------------------------|-----------------|
| Result version number | v1 (current) |
| This version publication date | 01 January 2020 |
| First version publication date | 01 January 2020 |

Trial information

Trial identification

| | |
|-----------------------|----------------------|
| Sponsor protocol code | GDW04/2014Amendment1 |
|-----------------------|----------------------|

Additional study identifiers

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

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Univeristy Hospitals Leuven |
| Sponsor organisation address | herestraat, leuven, Belgium, |
| Public contact | Anesthesie Research, Univeristy Hospitals Leuven, +32 16344620, christel.huygens@uzleuven.be |
| Scientific contact | Anesthesie Research, Univeristy Hospitals Leuven, +32 16344620, christel.huygens@uzleuven.be |

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 | 17 March 2017 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 16 January 2017 |
| Global end of trial reached? | Yes |
| Global end of trial date | 16 January 2017 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

Does a TAP-block offers superior analgesia in comparison with systemic administration of linisol after laparoscopic colo-rectal surgery.

Protection of trial subjects:

To prevent patient discomfort and distress, adequate follow-up and treatment was described in the protocol.

"Postoperative pain in the PACU and on the ward was treated with acetaminophen (15 mg/kg 4/day) and ketorolac (0.5mg/kg 3/day) using a fixed scheme. In addition, each patient received patient-controlled intravenous analgesia (PCIA) with morphine. If the postoperative numeric rating scale (NRS) for pain exceeded 3, an additional bolus of 1 mg of morphine (IV) was given on the PACU. If pain treatment was still insufficient, a clonidine bolus (1µg/kg) was given. PONV prophylaxis was performed with IV dexamethasone and IV ondansetron. PONV rescue treatment consisted of IV-droperidol (PACU) or IV-ondansetron (on the ward)."

Background therapy: -

Evidence for comparator: -

| | |
|---|--------------|
| Actual start date of recruitment | 14 July 2014 |
| 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 | Belgium: 125 |
| Worldwide total number of subjects | 125 |
| EEA total number of subjects | 125 |

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) | 87 |
| From 65 to 84 years | 38 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

between December 2014 and January 2017

Pre-assignment

Screening details:

125 patients undergoing laparoscopic colorectal surgery were included in this randomized, double-blind controlled clinical trial, patients were randomly allocated to either the quadratus lumborum group (QL-group)(n=50), the lidocaine group (L-group)(n=50) or the placebo group (P-group)(n=25)

Pre-assignment period milestones

| | |
|------------------------------|-----|
| Number of subjects started | 125 |
| Number of subjects completed | 125 |

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 |

Blinding implementation details:

To attain blinding of the patients and the investigators, patients in the QL-group and the P-group received a perioperative placebo infusion with saline at the same rate as the lidocaine infusion in the L-group. Moreover, the patients of both the L-group and the P-group received also a QL-block with saline.

Arms

| | |
|------------------------------|----------|
| Are arms mutually exclusive? | Yes |
| Arm title | QL-group |

Arm description:

Quadratus lumborum group: patients received TAP-block with ropivacaine 0.25% and clonidine 0.5µg/kg

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

Dosage and administration details:

In patients of the QL-group, a bilateral single shot QL-block was applied under ultrasound guidance before induction of anesthesia. At each side, 30 mL (in patients weighing > 55 kg) or 20 mL (in patients weighing < 55 kg) of ropivacaine 0.25% and clonidine 0.5 µg kg⁻¹ were injected using a 22G needle of 50mm length.

| | |
|------------------|---------|
| Arm title | L-group |
|------------------|---------|

Arm description:

Lidocaine group: patients received infusion with lidocaine 1.5 mg/kg (TAP block with placebo)

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

Dosage and administration details:

Patients in the L-group received an intravenous (IV) bolus injection of lidocaine 1.5 mg kg⁻¹ at induction of anesthesia followed by a continuous infusion of 1.5 mg kg⁻¹h⁻¹ which was continued until 4h after arrival at the postoperative anesthesia care unit (PACU).

| | |
|------------------|---------|
| Arm title | Control |
|------------------|---------|

Arm description:

Placebo group, Control group: Saline was given in TAP block, Saline was given in infusion. Only PCIA with morphine (as in QL-group and L-group).

| | |
|--|---------------------------------|
| Arm type | Placebo |
| Investigational medicinal product name | Saline |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Perineural use, Intravenous use |

Dosage and administration details:

To attain blinding of the patients and the investigators, patients in the QL-group and the P-group received a perioperative placebo infusion with saline at the same rate as the lidocaine infusion in the L-group. Moreover, the patients of both the L-group and the P-group received also a QL-block with saline.

| Number of subjects in period 1 | QL-group | L-group | Control |
|---------------------------------------|----------|---------|---------|
| Started | 50 | 50 | 25 |
| Completed | 50 | 50 | 25 |

Baseline characteristics

Reporting groups

| | |
|--|----------|
| Reporting group title | QL-group |
| Reporting group description: | |
| Quadratus lumborum group: patients received TAP-block with ropivacaine 0.25% and clonidine 0.5µg/kg | |
| Reporting group title | L-group |
| Reporting group description: | |
| Lidocaine group: patients received infusion with lidocaine 1.5 mg/kg (TAP block with placebo) | |
| Reporting group title | Control |
| Reporting group description: | |
| Placebo group, Control group: Saline was given in TAP block, Saline was given in infusion. Only PCIA with morphine (as in QL-group and L-group). | |

| Reporting group values | QL-group | L-group | Control |
|---|----------------|-------------|----------|
| Number of subjects | 50 | 50 | 25 |
| Age categorical | | | |
| age between 18 and 75 years Quadratus lumborum (n=50) 56 (48; 65) years lidocaine : (n=50) 60 (49; 68) years Placebo : (n=25) 62 (59;68) years | | | |
| Units: Subjects | | | |
| In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over | | | |
| Age continuous | | | |
| Units: years | | | |
| median | 59 | 60 | 62 |
| inter-quartile range (Q1-Q3) | 47.75 to 64.75 | 48 to 67.75 | 59 to 68 |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 18 | 23 | 11 |
| Male | 32 | 27 | 14 |
| ASA | | | |
| ASA classification | | | |
| Units: Subjects | | | |
| ASA 1 | 8 | 9 | 7 |
| ASA 2 | 34 | 30 | 14 |
| ASA 3 | 8 | 11 | 4 |

| | | | |
|--|----------------------|-------------------|----------------------|
| Weight Units: kilogram(s) median inter-quartile range (Q1-Q3) | 80 69 to 90 | 75 64 to 81 | 72 67 to 86 |
| BMI Units: kilogram(s)/square meter median inter-quartile range (Q1-Q3) | 26.4 23.9 to 29.4 | 25 23 to 27.2 | 25.4 24.2 to 28.4 |
| Height Units: cm median inter-quartile range (Q1-Q3) | 171 168 to 180 | 170 165 to 178 | 169 165 to 175 |

| | | | |
|---|-------|--|--|
| Reporting group values | Total | | |
| Number of subjects | 125 | | |
| Age categorical | | | |
| age between 18 and 75 years Quadratus lumborum (n=50) 56 (48; 65) years lidocaine : (n=50) 60 (49; 68) years Placebo : (n=25) 62 (59;68) years | | | |
| Units: Subjects | | | |
| In utero | 0 | | |
| Preterm newborn infants (gestational age < 37 wks) | 0 | | |
| Newborns (0-27 days) | 0 | | |
| Infants and toddlers (28 days-23 months) | 0 | | |
| Children (2-11 years) | 0 | | |
| Adolescents (12-17 years) | 0 | | |
| Adults (18-64 years) | 0 | | |
| From 65-84 years | 0 | | |
| 85 years and over | 0 | | |
| Age continuous Units: years median inter-quartile range (Q1-Q3) | - | | |
| Gender categorical Units: Subjects | | | |
| Female | 52 | | |
| Male | 73 | | |
| ASA | | | |
| ASA classification | | | |
| Units: Subjects | | | |
| ASA 1 | 24 | | |
| ASA 2 | 78 | | |
| ASA 3 | 23 | | |
| Weight Units: kilogram(s) median inter-quartile range (Q1-Q3) | - | | |
| BMI | | | |

| | | | |
|---------------------------------|---|--|--|
| Units: kilogram(s)/square meter | | | |
| median | | | |
| inter-quartile range (Q1-Q3) | - | | |
| Height | | | |
| Units: cm | | | |
| median | | | |
| inter-quartile range (Q1-Q3) | - | | |

End points

End points reporting groups

| | |
|--|----------|
| Reporting group title | QL-group |
| Reporting group description: Quadratus lumborum group: patients received TAP-block with ropivacaine 0.25% and clonidine 0.5µg/kg | |
| Reporting group title | L-group |
| Reporting group description: Lidocaine group: patients received infusion with lidocaine 1.5 mg/kg (TAP block with placebo) | |
| Reporting group title | Control |
| Reporting group description: Placebo group, Control group: Saline was given in TAP block, Saline was given in infusion. Only PCIA with morphine (as in QL-group and L-group). | |

Primary: Cumulative morphine usage

| | |
|--|---------------------------|
| End point title | Cumulative morphine usage |
| End point description: | |
| End point type | Primary |
| End point timeframe: 24 hours after surgery | |

| End point values | QL-group | L-group | Control | |
|--------------------------------------|-----------------|-----------------|-----------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 50 | 50 | 25 | |
| Units: milligram(s) | | | | |
| arithmetic mean (standard deviation) | 37.5 (± 28.4) | 40.2 (± 25) | 21.8 (± 17) | |

Statistical analyses

| | |
|---|---------------------------------|
| Statistical analysis title | Cumulative morphine consumption |
| Statistical analysis description: Cumulative morphine consumption the first 24 hours postoperatively | |
| Comparison groups | QL-group v L-group |
| Number of subjects included in analysis | 100 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence |
| P-value | = 0.15 |
| Method | t-test, 2-sided |

Secondary: Recovery of bowel movement

| | |
|-----------------|----------------------------|
| End point title | Recovery of bowel movement |
|-----------------|----------------------------|

End point description:

Time until defecation

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

End point timeframe:

Day of discharge (chart review)

| End point values | QL-group | L-group | Control | |
|---------------------------------------|-----------------|-----------------|-----------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 50 | 50 | 25 | |
| Units: day | | | | |
| median (inter-quartile range (Q1-Q3)) | 3 (2 to 5) | 3 (2 to 4) | 3 (2 to 5) | |

Statistical analyses

| | |
|----------------------------|-----------------------|
| Statistical analysis title | Time until defecation |
|----------------------------|-----------------------|

| | |
|-------------------|------------------------------|
| Comparison groups | QL-group v L-group v Control |
|-------------------|------------------------------|

| | |
|---|-----|
| Number of subjects included in analysis | 125 |
|---|-----|

| | |
|------------------------|---------------|
| Analysis specification | Pre-specified |
|------------------------|---------------|

| | |
|---------------|-------------|
| Analysis type | equivalence |
|---------------|-------------|

| | |
|---------|--------|
| P-value | = 0.84 |
|---------|--------|

| | |
|--------|-------------------------|
| Method | Wilcoxon (Mann-Whitney) |
|--------|-------------------------|

Secondary: Incidence of postoperative nausea and vomiting

| | |
|-----------------|--|
| End point title | Incidence of postoperative nausea and vomiting |
|-----------------|--|

End point description:

Incidence of PONV during first 24 hours postoperatively

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

End point timeframe:

24 hours after surgery

| End point values | QL-group | L-group | Control | |
|-----------------------------|-----------------|-----------------|-----------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 50 | 50 | 25 | |
| Units: number | | | | |
| PONV: yes | 30 | 35 | 16 | |
| PONV: No | 20 | 15 | 9 | |

Statistical analyses

| | |
|---|------------------------------|
| Statistical analysis title | incidence of PONV |
| Comparison groups | QL-group v L-group v Control |
| Number of subjects included in analysis | 125 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence |
| P-value | = 0.578 |
| Method | Fisher exact |

Secondary: Length of hospital stay

| | |
|------------------------|-------------------------|
| End point title | Length of hospital stay |
| End point description: | |
| End point type | Secondary |
| End point timeframe: | |
| Day of discharge | |

| | | | | |
|---------------------------------------|-----------------|-----------------|-----------------|--|
| End point values | QL-group | L-group | Control | |
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 50 | 50 | 25 | |
| Units: day | | | | |
| median (inter-quartile range (Q1-Q3)) | 4 (3 to 5) | 4 (4 to 5) | 4 (3 to 5) | |

Statistical analyses

| | |
|---|------------------------------|
| Statistical analysis title | Length of hospital stay |
| Comparison groups | QL-group v L-group v Control |
| Number of subjects included in analysis | 125 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.73 |
| Method | Wilcoxon (Mann-Whitney) |

Secondary: Clavien-Dindo Classification

| | |
|-----------------|------------------------------|
| End point title | Clavien-Dindo Classification |
|-----------------|------------------------------|

End point description:

Inhospital morbidity with the Clavien Dindo classification

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

End point timeframe:

Day of discharge

| End point values | QL-group | L-group | Control | |
|---------------------------------------|-----------------|-----------------|-----------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 50 | 50 | 25 | |
| Units: unit(s) | | | | |
| median (inter-quartile range (Q1-Q3)) | 0 (0 to 1) | 0 (0 to 0.75) | 0 (0 to 1) | |

Statistical analyses

| | |
|----------------------------|------------------------------|
| Statistical analysis title | Clavien Dindo classification |
|----------------------------|------------------------------|

| | |
|-------------------|------------------------------|
| Comparison groups | QL-group v L-group v Control |
|-------------------|------------------------------|

| | |
|---|-----|
| Number of subjects included in analysis | 125 |
|---|-----|

| | |
|------------------------|---------------|
| Analysis specification | Pre-specified |
|------------------------|---------------|

| | |
|---------------|-------------|
| Analysis type | equivalence |
|---------------|-------------|

| | |
|---------|---------|
| P-value | = 0.908 |
|---------|---------|

| | |
|--------|-------------------------|
| Method | Wilcoxon (Mann-Whitney) |
|--------|-------------------------|

Secondary: Cytokine IL-6 day 1

| | |
|-----------------|---------------------|
| End point title | Cytokine IL-6 day 1 |
|-----------------|---------------------|

End point description:

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

End point timeframe:

Day 1 after surgery

| End point values | QL-group | L-group | Control | |
|---------------------------------------|-----------------|-----------------|-----------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 50 | 50 | 25 | |
| Units: pg/mL | | | | |
| median (inter-quartile range (Q1-Q3)) | 15 (7 to 37) | 19 (11 to 39) | 36 (5 to 72) | |

Statistical analyses

| | |
|---|------------------------------|
| Statistical analysis title | Cytokine IL-6 Day 1 |
| Comparison groups | QL-group v L-group v Control |
| Number of subjects included in analysis | 125 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence |
| P-value | = 0.52 |
| Method | Wilcoxon (Mann-Whitney) |

Secondary: CRP

| | |
|------------------------|---|
| End point title | CRP |
| End point description: | C-reactive protein as inflammatory parameter at postoperative day 1 |
| End point type | Secondary |
| End point timeframe: | Day 1 after surgery |

| | | | | |
|---------------------------------------|-----------------|-----------------|-----------------|--|
| End point values | QL-group | L-group | Control | |
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 50 | 50 | 25 | |
| Units: milligram(s)/millilitre | | | | |
| median (inter-quartile range (Q1-Q3)) | 35 (17 to 55) | 42 (23 to 68) | 27 (19 to 50) | |

Statistical analyses

| | |
|---|------------------------------|
| Statistical analysis title | CRP day 1 |
| Comparison groups | QL-group v L-group v Control |
| Number of subjects included in analysis | 125 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence |
| P-value | = 0.31 |
| Method | Wilcoxon (Mann-Whitney) |

Secondary: Total number of morphine boli

| | |
|-----------------|-------------------------------|
| End point title | Total number of morphine boli |
|-----------------|-------------------------------|

End point description:

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

End point timeframe:

At removal of PCIA system

| End point values | QL-group | L-group | Control | |
|---------------------------------------|-----------------|-----------------|-----------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 50 | 50 | 25 | |
| Units: unit(s) | | | | |
| median (inter-quartile range (Q1-Q3)) | | | | |
| Delivered | 20 (13 to 31) | 22 (13 to 32) | 11 (5 to 22) | |
| Demanded | 23 (14 to 38) | 28 (14 to 49) | 12 (6 to 35) | |

Statistical analyses

| | |
|-----------------------------------|-------------------------|
| Statistical analysis title | Delivered morphine boli |
|-----------------------------------|-------------------------|

| | |
|-------------------|------------------------------|
| Comparison groups | QL-group v L-group v Control |
|-------------------|------------------------------|

| | |
|---|-----|
| Number of subjects included in analysis | 125 |
|---|-----|

| | |
|------------------------|---------------|
| Analysis specification | Pre-specified |
|------------------------|---------------|

| | |
|---------------|-------------|
| Analysis type | equivalence |
|---------------|-------------|

| | |
|---------|---------|
| P-value | = 0.005 |
|---------|---------|

| | |
|--------|-------------------------|
| Method | Wilcoxon (Mann-Whitney) |
|--------|-------------------------|

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Start: Enrollment

Stop: Until hospital discharge

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

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 21.1 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|----------|
| Reporting group title | QL-group |
|-----------------------|----------|

Reporting group description:

Quadratus lumborum group: patients received TAP-block with ropivacaine 0.25% and clonidine 0.5µg/kg

| | |
|-----------------------|---------|
| Reporting group title | L-group |
|-----------------------|---------|

Reporting group description:

Lidocaine group: patients received infusion with lidocaine 1.5 mg/kg (TAP block with placebo)

| | |
|-----------------------|---------|
| Reporting group title | Control |
|-----------------------|---------|

Reporting group description:

Placebo group, Control group: Saline was given in TAP block, Saline was given in infusion. Only PCIA with morphine (as in QL-group and L-group).

| Serious adverse events | QL-group | L-group | Control |
|---|-----------------|-----------------|-----------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 5 / 50 (10.00%) | 7 / 50 (14.00%) | 4 / 25 (16.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Peritonitis | | | |
| subjects affected / exposed | 1 / 50 (2.00%) | 1 / 50 (2.00%) | 1 / 25 (4.00%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Postoperative ileus | | | |
| subjects affected / exposed | 2 / 50 (4.00%) | 2 / 50 (4.00%) | 0 / 25 (0.00%) |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 4 | 0 / 4 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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

| Non-serious adverse events | QL-group | L-group | Control |
|---|---|----------------|-----------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 14 / 50 (28.00%) | 2 / 50 (4.00%) | 6 / 25 (24.00%) |
| Cardiac disorders | | | |
| Arrhythmia | Additional description: Arrhythmia as LAST (local anaesthetic systemic toxicity) | | |
| subjects affected / exposed | 2 / 50 (4.00%) | 0 / 50 (0.00%) | 0 / 25 (0.00%) |
| occurrences (all) | 2 | 2 | 2 |
| Nervous system disorders | | | |
| Metallic taste | Additional description: Metallic taste as symptom of LAST (local anaesthetic systemic toxicity) | | |
| subjects affected / exposed | 9 / 50 (18.00%) | 1 / 50 (2.00%) | 0 / 25 (0.00%) |
| occurrences (all) | 9 | 1 | 0 |
| Ear and labyrinth disorders | | | |
| Tinnitus | Additional description: LAST (local anaesthetic systemic toxicity) | | |
| subjects affected / exposed | 3 / 50 (6.00%) | 1 / 50 (2.00%) | 1 / 25 (4.00%) |
| occurrences (all) | 5 | 5 | 5 |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|------------------|---|
| 14 October 2014 | 1) Quadratus lumborum approach for TAP block 2) Time of TAP block at induction 3) Dosage of local anaesthetics 4) Timepoint blood sample 5) Serum ropivacain and lidocain measurement |
| 20 January 2015 | TAP block placement at induction with all patients (for the L-group and control, saline will be used) |
| 22 December 2015 | Lidocain determination on tissue that was isolated during surgery. |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/30004914>