



Clinical trial results:

Ropivacain 0,2% plus Dexamethason versus Ropivacain 0,2% plus Placebo in modified pectoral block - A randomized, double-blind, prospective trial

Summary

| | |
|--------------------------|-----------------|
| EudraCT number | 2018-003001-26 |
| Trial protocol | AT |
| Global end of trial date | 04 October 2021 |

Results information

| | |
|--------------------------------|------------------|
| Result version number | v1 (current) |
| This version publication date | 20 February 2023 |
| First version publication date | 20 February 2023 |

Trial information

Trial identification

| | |
|-----------------------|------|
| Sponsor protocol code | 1234 |
|-----------------------|------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT03700177 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Medical University of Innsbruck |
| Sponsor organisation address | Anichstraße 35, Innsbruck, Austria, 6020 |
| Public contact | Competence Center for Clinical Trials, University Hospital for Anaesthesia and Intensive Care, Anichstrasse 35, 6020 Innsbruck, 0043 512900370086, |
| Scientific contact | Competence Center for Clinical Trials, University Hospital for Anaesthesia and Intensive Care, Anichstrasse 35, 6020 Innsbruck, 0043 512900370086, |

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 | 04 October 2021 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 04 October 2021 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

to find out if dexamethason added to modified pectoral block (Pecs II) with ropivacaine 0.2% prolongs analgesic effect

Protection of trial subjects:

The visual analogue scale (VAS) to assess pain was assessed on admission to the post-anesthesia care unit (PACU), then hourly during the first 12 hours after PECS II block performance, and then every 12 hours until the end of follow-up after 84 hours. If VAS exceeded a value of 30 mm at any time, even without being actively asked by the medical staff, pain medications according to our study protocol were administered.

Generally spoken - every patient who needs a mastectomy receives a PECS II block - if not refused by the patient. For this study we didn't change the daily routine, neither in the operating theatre nor on the normal ward.

Background therapy:

-

Evidence for comparator:

-

| | |
|---|-------------------------------|
| Actual start date of recruitment | 07 January 2019 |
| Long term follow-up planned | Yes |
| Long term follow-up rationale | Efficacy, Scientific research |
| Long term follow-up duration | 12 Months |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|-------------|
| Country: Number of subjects enrolled | Austria: 60 |
| Worldwide total number of subjects | 60 |
| EEA total number of subjects | 60 |

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) | 34 |
| From 65 to 84 years | 22 |
| 85 years and over | 4 |

Subject disposition

Recruitment

Recruitment details:

Every friday, our operating theatre manager receives the OP schedule for the next week. Therefore, every friday, we checked the OP schedule for mastectomies in the following week and visited the patients on the day of their arrival in the hospital (usually the day before surgery).

Pre-assignment

Screening details:

Number of patients screened for inclusion were 118. On the day of their arrival in the clinic, they were all checked for eligibility to participate by one of our study members.

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? | Yes |
| Arm title | Intervention |

Arm description:

Ropivacaine + dexamethasone

| | |
|--|------------------------|
| Arm type | Active comparator |
| Investigational medicinal product name | Dexamethasone |
| Investigational medicinal product code | |
| Other name | Dexabene |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Perineural use |

Dosage and administration details:

For the dexamethasone group, 8 mg dexamethasone (2 ml) was added to 28 ml of ropivacaine 0.2%.

| | |
|------------------|---------|
| Arm title | Placebo |
|------------------|---------|

Arm description:

Ropivacaine + saline solution 0.9%

| | |
|--|------------------------|
| Arm type | Placebo |
| Investigational medicinal product name | Saline solution 0.9% |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Perineural use |

Dosage and administration details:

For the placebo group, 2 ml of saline solution 0.9% was added to 28 ml of ropivacaine 0.2%.

| Number of subjects in period 1 | Intervention | Placebo |
|--|--------------|---------|
| Started | 30 | 30 |
| Completed | 28 | 30 |
| Not completed | 2 | 0 |
| Did not receive allocated intervention | 2 | - |

Baseline characteristics

Reporting groups

| | |
|--|--------------|
| Reporting group title | Intervention |
| Reporting group description: Ropivacaine + dexamethasone | |
| Reporting group title | Placebo |
| Reporting group description: Ropivacaine + saline solution 0.9% | |

| Reporting group values | Intervention | Placebo | Total |
|--|--------------|--------------|-------|
| Number of subjects | 30 | 30 | 60 |
| Age categorical | | | |
| Units: Subjects | | | |
| In utero | 0 | 0 | 0 |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | 0 |
| Newborns (0-27 days) | 0 | 0 | 0 |
| Infants and toddlers (28 days-23 months) | 0 | 0 | 0 |
| Children (2-11 years) | 0 | 0 | 0 |
| Adolescents (12-17 years) | 0 | 0 | 0 |
| Adults (18-64 years) | 19 | 15 | 34 |
| From 65-84 years | 9 | 13 | 22 |
| 85 years and over | 2 | 2 | 4 |
| Age continuous | | | |
| Units: years | | | |
| arithmetic mean | 59.0 | 69.0 | |
| full range (min-max) | 51.3 to 74.8 | 56.0 to 74.0 | - |
| Gender categorical | | | |
| female patients undergoing unilateral mastectomy who meet inclusion criteria and want to participate | | | |
| Units: Subjects | | | |
| Female | 30 | 30 | 60 |
| Male | 0 | 0 | 0 |

End points

End points reporting groups

| | |
|------------------------------------|--------------|
| Reporting group title | Intervention |
| Reporting group description: | |
| Ropivacaine + dexamethasone | |
| Reporting group title | Placebo |
| Reporting group description: | |
| Ropivacaine + saline solution 0.9% | |

Primary: Total morphine equivalent consumption in the first 72 hours

| | |
|------------------------|---|
| End point title | Total morphine equivalent consumption in the first 72 hours |
| End point description: | |
| End point type | Primary |
| End point timeframe: | |
| 72 hours | |

| End point values | Intervention | Placebo | | |
|-----------------------------|----------------------|----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 28 | 30 | | |
| Units: mg | | | | |
| median (standard deviation) | 11.89 (\pm 13.03) | 11.90 (\pm 10.81) | | |

Statistical analyses

| | |
|---|----------------------------------|
| Statistical analysis title | MME - 72 h |
| Comparison groups | Intervention v Placebo |
| Number of subjects included in analysis | 58 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence |
| P-value | = 0.831 |
| Method | Wilcoxon (Mann-Whitney) |
| Parameter estimate | Median difference (final values) |
| Confidence interval | |
| level | 95 % |

Adverse events

Adverse events information

Timeframe for reporting adverse events:

84h postoperative

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

Dictionary used

| | |
|-----------------|-------|
| Dictionary name | CTCAE |
|-----------------|-------|

| | |
|--------------------|-----|
| Dictionary version | 5.0 |
|--------------------|-----|

Reporting groups

| | |
|-----------------------|--------------|
| Reporting group title | Intervention |
|-----------------------|--------------|

Reporting group description:

Ropivacaine + dexamethasone

| | |
|-----------------------|---------|
| Reporting group title | Placebo |
|-----------------------|---------|

Reporting group description:

Ropivacaine + saline solution 0.9%

| Serious adverse events | Intervention | Placebo | |
|---|----------------|----------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 30 (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 | Intervention | Placebo | |
|---|-----------------|------------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 5 / 28 (17.86%) | 10 / 30 (33.33%) | |
| Cardiac disorders | | | |
| Hypertension | | | |
| subjects affected / exposed | 3 / 28 (10.71%) | 7 / 30 (23.33%) | |
| occurrences (all) | 10 | 10 | |
| General disorders and administration site conditions | | | |
| Shivering | | | |
| subjects affected / exposed | 1 / 28 (3.57%) | 0 / 30 (0.00%) | |
| occurrences (all) | 1 | 1 | |
| Gastrointestinal disorders | | | |

| | | | |
|-----------------------------|----------------|-----------------|--|
| PONV | | | |
| subjects affected / exposed | 1 / 28 (3.57%) | 3 / 30 (10.00%) | |
| occurrences (all) | 4 | 4 | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|------------------|--|
| 10 November 2018 | We found out that our patients are being followed-up by the gynecologists every 3 months for approximately 1 year, so we decided that we design a questionnaire to ask for patient satisfaction and pain. By extending the observation period, we had to make a substantial amendment. |

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/34872040>