



Clinical trial results:

Jatkuvan haavapuudutuksen vaikutukset tavanomaiseen kipulääkitykseen lapsipotilailla sydänleikkauksen jälkeen

Summary

| | |
|--------------------------|-----------------|
| EudraCT number | 2008-008380-94 |
| Trial protocol | FI |
| Global end of trial date | 07 October 2014 |

Results information

| | |
|-----------------------------------|---|
| Result version number | v1 (current) |
| This version publication date | 01 February 2020 |
| First version publication date | 01 February 2020 |
| Summary attachment (see zip file) | Ropivacaine infusion for post sternotomy pain (Mattila_et_al-2016-Pediatric_Anesthesia.pdf) |

Trial information

Trial identification

| | |
|-----------------------|----------------------|
| Sponsor protocol code | Sternumhaavapuudutus |
|-----------------------|----------------------|

Additional study identifiers

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

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Helsinki University Hospital |
| Sponsor organisation address | Stenbäckinkatu 11, Helsinki, Finland, 00029 HUS |
| Public contact | Department of Anesthesia and Intensive care, Helsinki University Hospital, +358 0504271648, arja.hiller@hus.fi |
| Scientific contact | Department of Anesthesia and Intensive care, Helsinki University Hospital, +358 0504271648, arja.hiller@hus.fi |

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 | 31 May 2015 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 07 October 2014 |
| Global end of trial reached? | Yes |
| Global end of trial date | 07 October 2014 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

Examine whether the continuous infusion of 0.2% ropivacaine decreases daily morphine consumption for 72 h in children who were undergoing ASd closure.

Protection of trial subjects:

The study was approved by the institutional Ethics Committee

Background therapy: -

Evidence for comparator: -

| | |
|---|------------------|
| Actual start date of recruitment | 02 November 2009 |
| 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 | Finland: 49 |
| Worldwide total number of subjects | 49 |
| EEA total number of subjects | 49 |

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) | 49 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 0 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 49 children aged 1-9 years of ASA physical status II-IV who were undergoing ASD repair were enrolled

Period 1

| | |
|------------------------------|---|
| Period 1 title | Postoperative (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 |

Blinding implementation details:

Enrolled children were randomly assigned to a treatment by the sealed-envelope method. The study design was a series of blocks of fours, whereby a patient randomly received either a continuous wound infusion or ropivacaine or of saline. A nurse anesthetist who did not participate in the postoperative care of the enrolled children prepared all study medications according to the assigned group treatments.

Arms

| | |
|------------------------------|--------|
| Are arms mutually exclusive? | Yes |
| Arm title | saline |

Arm description:

continuous ropivacaine infusion was compared with same amount (ml) saline

| | |
|--|-------------|
| Arm type | Placebo |
| Investigational medicinal product name | ropivacain |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Infusion |
| Routes of administration | Unknown use |

Dosage and administration details:

drugs were given to wound catheter parallel into the sternal wound above mediastinum
0.2% ropivacaine as a bolus 0.5 ml/kg and thereafter as continuous infusion 0.3-0.4 mg/kg/h

| | |
|--|-------------|
| Investigational medicinal product name | saline |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Infusion |
| Routes of administration | Unknown use |

Dosage and administration details:

After skin closure, the surgeon injected a bolus of saline 0.5 ml/kg to wound catheter and thereafter continuous infusion of saline 1-7 ml/h depending on the weight of a child.

| | |
|------------------|-------------|
| Arm title | ropivacaine |
|------------------|-------------|

Arm description:

Continuous ropivacaine infusion was compared with same amount (ml) of saline

| | |
|--|-------------------|
| Arm type | Active comparator |
| Investigational medicinal product name | ropivacain |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Infusion |
| Routes of administration | Unknown use |

Dosage and administration details:

drugs were given to wound catheter parallel into the sternal wound above mediastinum
0.2% ropivacaine as a bolus 0.5 ml/kg and thereafter as continuous infusion 0.3-0.4 mg/kg/h

| Number of subjects in period 1 | saline | ropivacaine |
|---------------------------------------|--------|-------------|
| Started | 23 | 26 |
| Completed | 23 | 26 |

Baseline characteristics

End points

End points reporting groups

| | |
|--|-------------|
| Reporting group title | saline |
| Reporting group description: continuous ropivacaine infusion was compare with same amount (ml) saline | |
| Reporting group title | ropivacaine |
| Reporting group description: Continuous ropivacaine infusion was compared with same amount (ml) of saline | |

Primary: change in morphine consumption between groups during 72 h

| | | | |
|----------------------------|---|-------------|--|
| End point title | change in morphine consumption between groups during 72 h | | |
| End point description: | | | |
| Morphine consumption mg/kg | Control | Ropivacaine | |
| 0-24 h | 0.63 (0.30) | 0.68 (0.25) | |
| 24-48 h | 0.16 (0.10) | 0.20 (0.18) | |
| 48-72 h | 0.06 (0.07) | 0.07 (0.12) | |
| End point type | Primary | | |
| End point timeframe: | | | |
| 72 h | | | |

| End point values | saline | ropivacaine | | |
|----------------------------------|---------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 23 | 26 | | |
| Units: mg /kg | | | | |
| number (confidence interval 95%) | | | | |
| morphine consumption | 0.63 (0.43 to 0.71) | 0.68 (0.48 to 0.79) | | |

Statistical analyses

| | |
|---|----------------------|
| Statistical analysis title | Statistical analysis |
| Statistical analysis description: Comparisons between the groups were performed using the Student's t-test to compare means, the Mann-Whitney U-test to compare distributions nonparametrically, and Fisher's exact test when appropriate. Normality of the distribution was assessed by Shapiro-Wilk W test, and depending on the results, either parametric or nonparametric analysis was performed. Data on demographics, surgery, anesthetics and doses of drug administered were analyzed using Student's t-test. | |
| Comparison groups | saline v ropivacaine |

| | |
|---|--------------------------------|
| Number of subjects included in analysis | 49 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | < 0.5 ^[1] |
| Method | Fisher exact |
| Parameter estimate | Mean difference (final values) |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.05 |
| upper limit | 0.05 |
| Variability estimate | Standard deviation |

Notes:

[1] - A P-value <0.05 were considered significant.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

During 24 hrs hourly, 24-72 h every fourth hour

Adverse event reporting additional description:

Daily questionnaire for ward nurses

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

Dictionary used

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

| | |
|--------------------|---|
| Dictionary version | 1 |
|--------------------|---|

Reporting groups

| | |
|-----------------------|-------------|
| Reporting group title | ropivacaine |
|-----------------------|-------------|

Reporting group description: -

| | |
|-----------------------|---------|
| Reporting group title | control |
|-----------------------|---------|

Reporting group description: -

| Serious adverse events | ropivacaine | control | |
|---|----------------|----------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 23 (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 | ropivacaine | control | |
|---|------------------|------------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 15 / 26 (57.69%) | 18 / 23 (78.26%) | |
| General disorders and administration site conditions | | | |
| nausea and vomiting | | | |
| subjects affected / exposed | 15 / 26 (57.69%) | 18 / 23 (78.26%) | |
| occurrences (all) | 57 | 78 | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported