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:

continuos ropivacaine infusion was compare 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 continuos infuusion 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 continuos infuusion 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:	
continuos 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