Clinical trial results:
Posttonsillectomy peritonsillar bupivacaine infiltration for pain relief in children.

Summary

EudraCT number	2011-005467-25
Trial protocol	BE
Global end of trial date	30 September 2016

Results information

Result version number	v1 (current)
This version publication date	30 December 2019
First version publication date	30 December 2019

Trial information

Trial identification

Sponsor protocol code	AT10-2011

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	University Hospitals Leuven
Sponsor organisation address	Herestraat 49, Leuven, Belgium,
Public contact	Anesthesia Research, University Hospitals Leuven, +32 16344620, christel.huygens@uzleuven.be
Scientific contact	Anesthesia Research, University 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	25 November 2016
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	30 September 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To compare the proportion of patients who receive piritramide IV the first six hours after the surgery.

Protection of trial subjects:

All patients received prophylactic pain therapy consisting of paracetamol and ketorolac.
Pain scores were measured frequently. Adverse events were evaluated untill 14 days postoperatively

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	16 January 2012
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: 200
Worldwide total number of subjects	200
EEA total number of subjects	200

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)	200
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:

Children between 4-10years old undergoing adenotonsillectmy in the day care centre of UZ Leuven

Pre-assignment

Screening details:

In this prospective double-blind randomized controlled trial we included 200 children, ASA status 1 en 2 undergoing elective adeno-tonsillectomy in an ambulatory setting

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Tramadol

Arm description:

Patients allocated to the tramadol group received a bolus of 3 mg/kg tramadol IV intraoperatively

Arm type	Experimental
Investigational medicinal product name	tramadol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous bolus use

Dosage and administration details:

3 mg/kg tramadol diluted in saline to a total volume of 5 ml, injected intravenously as a bolus

Arm title	Local infiltration analgesia

Arm description:

At the end of surgery the tonsllar loge was infiltrated with bupivacaine 0.25% 5 ml

Arm type	Experimental
Investigational medicinal product name	bupivacaine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Infiltration

Dosage and administration details:

Infiltration of bupivacaine 0.25% 5 ml

Number of subjects in period 1	Tramadol	Local infiltration analgesia
Started	100	100
Completed	100	100

Baseline characteristics

Reporting groups	
Reporting group title	Tramadol
Reporting group description:	
Patients allocated to the tramadol group received a bolus of 3 mg/kg tramadol IV intraoperatively	
Reporting group title	Local infiltration analgesia
Reporting group description:	
At the end of surgery the tonsllar loge was infiltrated with bupivacaine 0.25% 5 ml	

Reporting group values	Tramadol	Local infiltration analgesia	Total
Number of subjects	100	100	200
Age categorical 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	5	5	
inter-quartile range (Q1-Q3)	4 to 6	4 to 7	-
Gender categorical Units: Subjects			
Female	42	48	90
Male	58	52	110
ASA Units: Subjects			
ASA 1	93	94	187
ASA 2	7	6	13
weight Units: kilograms			
median	19	20.5	
inter-quartile range (Q1-Q3)	17 to 21.5	17.1 to 25	-

End points

End points reporting groups

Reporting group title	Tramadol
Reporting group description:	
Patients allocated to the tramadol group received a bolus of 3 mg/kg tramadol IV intraoperatively	
Reporting group title	Local infiltration analgesia
Reporting group description:	
At the end of surgery the tonsllar loge was infiltrated with bupivacaine 0.25% 5 ml	

Primary: Number of patients needing piritramide postoperatively

End point title	Number of patients needing piritramide postoperatively
End point description:	
End point type	Primary
End point timeframe:	
Postoperatively in the DSU untill 24 hours postoperatively at home	

End point values	Tramadol	Local infiltration analgesia		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	100	100		
Units: number				
piritramide	57	81		

Statistical analyses

Statistical analysis title	need for piritramide postoperatively
Comparison groups	Tramadol v Local infiltration analgesia
Number of subjects included in analysis	200
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	Fisher exact

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
POstoperatively in the day care unit, until 2 weeks postoperatively	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	21.1

Reporting groups	
Reporting group title	Tramadol
Reporting group description: -	
Reporting group title	Local infiltrationanalgesia
Reporting group description: -	

Serious adverse events	Tramadol	Local infiltrationanalgesia	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (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: 3 %

Non-serious adverse events	Tramadol	Local infiltrationanalgesia	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 100 (8.00%)	6 / 100 (6.00%)	
Surgical and medical procedures			
post tonsillectomy hemorrage			
subjects affected / exposed	8 / 100 (8.00%)	6 / 100 (6.00%)	
occurrences (all)	8	6	

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

Online references

http://www.ncbi.nlm.nih.gov/pubmed/30640245