Clinical trial results:
Dorsal penile nerve block(DPNB) for circumcision: a comparison of ultrasound-guided vs. landmark technique.

Summary

EudraCT number	2012-001217-16
Trial protocol	BE
Global end of trial date	30 November 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	AT032012

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	Anesthesie Research, UZLeuven, 0032 016344620, christel.huygens@uzleuven.be
Scientific contact	Anesthesie Research, UZLeuven, 0032 016344620, 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	20 December 2016
Is this the analysis of the primary completion data?	No

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

Notes:

General information about the trial

Main objective of the trial:

confirming the hypothesis that the US-guided Dorsal penile nerve block will provide better and longer postoperative analgesia in circumcision patients when compared to the landmark technique.

Protection of trial subjects:

All patients received paracetamol for pain treatment intraoperatively.
Pain scores were measured frequently

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 June 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: 310
Worldwide total number of subjects	310
EEA total number of subjects	310

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)	132
Children (2-11 years)	178
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:

Children between 52 weeks podtconception and 11 years , ASA 1-2 undergoing elctive circumcision

Period 1

Period 1 title	overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	LM-DPNB

Arm description: -

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

Dosage and administration details:

0.1ml/kg at both sides into the subpubic space

Arm title	US-DPNB

Arm description: -

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

Dosage and administration details:

0.1ml/kg at both sides into the subpubic space

Number of subjects in period 1	LM-DPNB	US-DPNB
Started	155	155
Completed	155	155

Baseline characteristics

Reporting groups

Reporting group title	overall trial

Reporting group description: -

Reporting group values	overall trial	Total	
Number of subjects	310	310	
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: months			
median	28.5		
inter-quartile range (Q1-Q3)	15 to 56.75	-	
Gender categorical Units: Subjects			
Female	0	0	
Male	310	310	

Subject analysis sets

Subject analysis set title	LM-DPNB
Subject analysis set type	Full analysis
Subject analysis set description: primary outcome	
Subject analysis set title	US-DPNB
Subject analysis set type	Full analysis
Subject analysis set description: primary outcome	

Reporting group values	LM-DPNB	US-DPNB	
Number of subjects	155	155	
Age categorical 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: months			
median	29	28	
inter-quartile range (Q1-Q3)	14.5 to 56.5	15.5 to 56.5	
Gender categorical Units: Subjects			
Female	0	0	
Male	155	155	

End points

End points reporting groups

Reporting group title	LM-DPNB
Reporting group description: -	
Reporting group title	US-DPNB
Reporting group description: -	
Subject analysis set title	LM-DPNB
Subject analysis set type	Full analysis
Subject analysis set description: primary outcome	
Subject analysis set title	US-DPNB
Subject analysis set type	Full analysis
Subject analysis set description: primary outcome	

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 until discharge	

End point values	LM-DPNB	US-DPNB		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	155	155		
Units: number	59	72		

Statistical analyses

Statistical analysis title	need for piritramide postoperatively
Comparison groups	LM-DPNB v US-DPNB
Number of subjects included in analysis	310
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	Fisher exact

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: Intraoperatively and postoperatively until 24 hours	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	21.1

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

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: All patients were observed for adverse during the first 24 hours postoperatively.
No technique related adverse events were reported

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