Clinical trial results:
Ultrasound Guided Caudal Blockade in Children between 30 and 50kg: A Feasibility Study

Summary

EudraCT number	2013-002359-14
Trial protocol	AT
Global end of trial date	28 September 2015

Results information

Result version number	v1 (current)
This version publication date	05 March 2021
First version publication date	05 March 2021

Trial information

Trial identification

Sponsor protocol code	1.0

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-
Other trial identifiers	DRKS number: DRKS00005021

Notes:

Sponsors

Sponsor organisation name	Medical University of Vienna
Sponsor organisation address	Spitalgasse 23, Vienna, Austria, 1090
Public contact	Klaus Markstaller(Sponsor), contact person: Daniela Marhofer, Med. Universität Wien, Universitätsklinik für Anästhesie, Allg. Intesnivmedizin&Schmerztherapie, +43 14040041020, daniela.marhofer@meduniwien.ac.at
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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	28 September 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	28 September 2015
Global end of trial reached?	Yes
Global end of trial date	28 September 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Caudal block is possible for children between 30 and 50kg body weight, no additional analgesic drugs were required during surgery

Protection of trial subjects:

Anonymisation of the data, no name will be published, only iniditals

Background therapy:

Premedication consisted in midazolam orally or iv. All children received an infusion of Elo-Mel isotone at a rate of 5 ml kg-1 h-1. General anaesthesia was induced with propofol 10 mg •ml-1 at 2−4 mg kg-1 and fentanyl 1 µg kg-1 to facilitate the insertion of a laryngeal mask. Anaesthesia was then maintained with sevoflurane at 1 MAC (end-expiratory) via laryngeal mask and spontaneous respiration. Where pre-induction establishment of a venous access was not possible, inhalation anaesthesia with sevoflurane 8 vol% was used for induction.

Evidence for comparator:

Caudal anaesthesia is a common anaesthesiological procedure for children less than 25kg body weight

Actual start date of recruitment	30 July 2014
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Austria: 20
Worldwide total number of subjects	20
EEA total number of subjects	20

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)	9

Adolescents (12-17 years)	11
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients who have to undergo subumbilical surgery with a body weight 30-50kg are recruited in the Deaprtment of paediatric surgery.

Pre-assignment

Screening details:

Subjects undergo subumbilical surgery with a body weight 30-50kg

Pre-assignment period milestones

Number of subjects started	20
Number of subjects completed	

Period 1

Period 1 title	baseline (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Caudal block for children with a body weight 30-50kg

Arm description:

Children with a body weight 30-50kg has to undergo caudal block are recruitted

Arm type	Experimental
Investigational medicinal product name	Ropivacaine 3.1mg/ml
Investigational medicinal product code	Ropivacaine
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Epidural use

Dosage and administration details:

1ml/kg bodyweight Ropivacaine 3.1mg/ml

Number of subjects in period 1	Caudal block for children with a body weight 30-50kg
Started	20
Completed	20

Baseline characteristics

Reporting groups

Reporting group title	baseline

Reporting group description: -

Reporting group values	baseline	Total	
Number of subjects	20	20	
Age categorical			
Children from 2 to 17 years (2groups: 2-11 years old and 12-17 years old)			
Units: Subjects			
Children (2-11 years)	9	9	
Adolescents (12-17 years)	11	11	
Gender categorical			
girls and boys are included			
Units: Subjects			
Female	3	3	
Male	17	17	

Subject analysis sets

Subject analysis set title	Overall trial
Subject analysis set type	Per protocol

Subject analysis set description:

Children with a body weight 30-50kg has to undergo caudal block are recruitted

Reporting group values	Overall trial		
Number of subjects	20		
Age categorical			
Children from 2 to 17 years (2groups: 2-11 years old and 12-17 years old)			
Units: Subjects			
Children (2-11 years)	9		
Adolescents (12-17 years)	11		
Gender categorical			
girls and boys are included			
Units: Subjects			
Female	3		
Male	17		

End points

End points reporting groups

Reporting group title	Caudal block for children with a body weight 30-50kg
Reporting group description: Children with a body weight 30-50kg has to undergo caudal block are recruitted	
Subject analysis set title	Overall trial
Subject analysis set type	Per protocol
Subject analysis set description: Children with a body weight 30-50kg has to undergo caudal block are recruitted	

Primary: Feasibility of a successful block

End point title	Feasibility of a successful block
End point description: Feasibility of the caudal blockades in children with a body weight 30-50kg. If there are any movements of extremities or haemodynamic changes of 15% at time of skin incision the caudal block would have been considered as "unsuccessful".	
End point type	Primary
End point timeframe: The block has to work 15 minutes after performing the block	

End point values	Caudal block for children with a body weight 30-50kg	Overall trial		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	20	20		
Units: yes or not	20	20		

Statistical analyses

Statistical analysis title	Descriptive Analysis, Pearson's correlation
Statistical analysis description: The presence of a normal distribution was checked by a one-sample Kolmogorov-Smirnov test, using statistical software (IBM SPSS Statistics, v. 20; IBM, Armonk, NY, USA). All data were descriptively analysed. Pearson’s correlation coefficient was used to evaluate associations between pharmacodynamics and body weight	
Comparison groups	Caudal block for children with a body weight 30-50kg v Overall trial
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	other[1]
P-value	= 0 [2]
Method	Pearson's correlation
Parameter estimate	correlation coefficient

Notes:
[1] - clinical case series study of feasibility
[2] - no p-value

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

study period

Adverse event reporting additional description:

failed block is predefined by a movement while skin inzision, preoperatively monitoring of the vital parameters (non invasive blood pressure, egg, oxygen saturation), neurological evaluation

Assessment type	Systematic

Dictionary used

Dictionary name	n.a.
Dictionary version	0

Reporting groups

Reporting group title	failed block

Reporting group description:

failed block is predefined by a movment while the skin incision

Serious adverse events	failed block		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 2 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	failed block		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 2 (0.00%)		

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: clinical case series study of feasibility none AE

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
06 February 2014	Protocol change: after 4 participants an amendment was done: instead of caudal block and sedation, general anaesthesia with larnygeal mask but under spontanous ventilation would be done. Reason: the need of sedation medication was too high, general anaesthesia under spontanous ventilation would be better and easier

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

no limitations and caveats

Notes: