



## Clinical trial results:

### The effect of audio-visual brainwave entrainment on sedation level in children

#### Summary

EudraCT number	2012-005303-40
Trial protocol	AT
Global end of trial date	31 May 2016

#### Results information

Result version number	v1 (current)
This version publication date	12 July 2020
First version publication date	12 July 2020

#### Trial information

##### Trial identification

Sponsor protocol code	3.0
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##### Additional study identifiers

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

Notes:

#### Sponsors

Sponsor organisation name	Medical University of Vienna
Sponsor organisation address	Währinger Gürtel 18-20, Wien, Austria, 1090
Public contact	Werner Schmid, Universitätsklinik für Anästhesie, Allgemeine Intensivmedizin und Schm, +43 1404004102, werner.schmid@meduniwien.ac.at
Scientific contact	Werner Schmid, Universitätsklinik für Anästhesie, Allgemeine Intensivmedizin und Schmerztherapie, 6763796475 1404004102, werner.schmid@meduniwien.ac.at

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:

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**Results analysis stage**

Analysis stage	Final
Date of interim/final analysis	30 June 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 May 2016
Global end of trial reached?	Yes
Global end of trial date	31 May 2016
Was the trial ended prematurely?	No

Notes:

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**General information about the trial**

Main objective of the trial:

Additionally added audio-visual brainwave entrainment on children who are undergoing surgery with caudal anesthesia may reduce the demand of sedation drugs to maintain the same level of sedation.

Protection of trial subjects:

The subjects were observed and monitored closely during the whole surgical procedure with appropriate medical treatment readily available

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 September 2013
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

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**Population of trial subjects**

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**Subjects enrolled per country**

Country: Number of subjects enrolled	Austria: 49
Worldwide total number of subjects	49
EEA total number of subjects	49

Notes:

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**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:

From September 2013 to May 2016, we considered 54 boys aged 1 to 6 years who were scheduled for elective subumbilical procedures under caudal anaesthesia

### 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	Investigator, Subject

### Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	Brainwave entrainment

Arm description:

binaural beats applied in the study group commenced at a frequency difference of 10 Hz, were then reduced by 2 Hz every 150 seconds until the software setting was down to 2 Hz, and were finally maintained at a steady state oscillating between 1 and 2 Hz

Arm type	Experimental
Investigational medicinal product name	Propofol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Emulsion for injection
Routes of administration	Intravenous use

Dosage and administration details:

binaural beats were not applied in the control group

<b>Arm title</b>	Control
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Arm description:

binaural beats were not applied in the control group

Arm type	Placebo
Investigational medicinal product name	Propofol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Emulsion for injection
Routes of administration	Intravenous use

Dosage and administration details:

binaural beats were not applied in the control group

<b>Number of subjects in period 1</b>	Brainwave entrainment	Control
Started	23	26
Completed	23	26

## Baseline characteristics

### Reporting groups

Reporting group title	Brainwave entrainment
Reporting group description: binaural beats applied in the study group commenced at a frequency difference of 10 Hz, were then reduced by 2 Hz every 150 seconds until the software setting was down to 2 Hz, and were finally maintained at a steady state oscillating between 1 and 2 Hz	
Reporting group title	Control
Reporting group description: binaural beats were not applied in the control group	

Reporting group values	Brainwave entrainment	Control	Total
Number of subjects	23	26	49
Age categorical Units: Subjects			
Infants and toddlers (28 days-23 months)	6	10	16
Children (2-11 years)	17	16	33
Gender categorical Units: Subjects			
Female	0	0	0
Male	23	26	49

### Subject analysis sets

Subject analysis set title	dose requirements for continuous propofol infusion
Subject analysis set type	Per protocol
Subject analysis set description: The primary outcome parameter of this study were the dose requirements for continuous propofol infusion (in milligrams per kilogram body weight per minute) to maintain bispectral index scores between 60 and 70.	

Reporting group values	dose requirements for continuous propofol infusion		
Number of subjects	49		
Age categorical Units: Subjects			
Infants and toddlers (28 days-23 months)	16		
Children (2-11 years)	33		
Gender categorical Units: Subjects			
Female	0		
Male	49		

## End points

### End points reporting groups

Reporting group title	Brainwave entrainment
Reporting group description: binaural beats applied in the study group commenced at a frequency difference of 10 Hz, were then reduced by 2 Hz every 150 seconds until the software setting was down to 2 Hz, and were finally maintained at a steady state oscillating between 1 and 2 Hz	
Reporting group title	Control
Reporting group description: binaural beats were not applied in the control group	
Subject analysis set title	dose requirements for continuous propofol infusion
Subject analysis set type	Per protocol
Subject analysis set description: The primary outcome parameter of this study were the dose requirements for continuous propofol infusion (in milligrams per kilogram body weight per minute) to maintain bispectral index scores between 60 and 70.	

### Primary: dose requirements for continuous propofol infusion to maintain bispectral index scores between 60 and 70

End point title	dose requirements for continuous propofol infusion to maintain bispectral index scores between 60 and 70
End point description:	
End point type	Primary
End point timeframe: During surgery	

End point values	Brainwave entrainment	Control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	26		
Units: milligrams/kilogram body weight/min				
number (confidence interval 95%)	0.05 (0.04 to 0.06)	0.07 (0.06 to 0.08)		

### Statistical analyses

Statistical analysis title	Student's t-test or a Mann-Whitney U-t
Comparison groups	Brainwave entrainment v Control
Number of subjects included in analysis	49
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.5
Method	t-test, 2-sided



## Adverse events

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### Adverse events information<sup>[1]</sup>

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Timeframe for reporting adverse events:

During surgery and postoperative recovery

Assessment type	Systematic
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### Dictionary used

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Dictionary name	MedDRA
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Dictionary version	14.1
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Frequency threshold for reporting non-serious adverse events: 1 %

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#### 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: Considering the type of non-pharmacological and non-invasive intervention by applying binaural beats no adverse events were expected and experienced



## **More information**

### **Substantial protocol amendments (globally)**

Were there any global substantial amendments to the protocol? No

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### **Interruptions (globally)**

Were there any global interruptions to the trial? No

### **Limitations and caveats**

None reported