



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 |
|-----------------------|-----|

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:

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:

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:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|-------------|
| Country: Number of subjects enrolled | Austria: 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:

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 |
| Arm title | 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

| | |
|------------------|---------|
| Arm title | Control |
|------------------|---------|

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

| Number of subjects in period 1 | 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

Adverse events information^[1]

Timeframe for reporting adverse events:

During surgery and postoperative recovery

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

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|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|------|
| Dictionary version | 14.1 |
|--------------------|------|

Frequency threshold for reporting non-serious adverse events: 1 %

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

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported