Cyclopentolate induced EEG changes in children

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To compare the EEG pattern after administration of cyclopentolate with the EEG pattern after placebo eye-drops.Primary outcomeEEG pattern changes after administration of two drops of cyclopentolate1% compared with placebo.Secondary outcomes- Pattern...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON41638

Source
ToetsingOnline

Brief title
Cycloplegic EEG

Condition

- Other condition
- Cardiac arrhythmias

Synonym
EEG changes. Adverse events central nervus system

Health condition

Bijwerkingen centraal zenuwstelstel; EEG veranderingen

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Haaglanden
Source(s) of monetary or material Support: Medisch Centrum Haaglanden

Intervention

Keyword: Cyclopentolate, Cycloplegics, EEG, Side effects

Outcome measures

Primary outcome

Primary outcome is to detect the presence of EEG pattern changes after administration of 2 drops of cyclopentolate 1%.

Secondary outcome

Secondary outcomes are the kind of EEG pattern changes, detection of time of onset of EEG pattern changes, detection of the amount and depth of EEG pattern changes and detect factors that influences onset of- and/or changes in EEG pattern. Furthermore detection of ECG changes and time of onset of these ECG changes.

Study description

Background summary

Cyclopentolate is the most frequently used cycloplegic eye-drops in children. About 10% of the subjects suffer from side effects (SE). These SE almost exclusively involve the central nervous system (CNS). The risk for SE increases with younger age and in the presence of low BMI. The most frequently reported SE is drowsiness and hyperactivity. CNS changes can be recorded by EEG. There are no studies describing EEG changes after cyclopentolate. There however studies describing EEG changes after IV administration of atropine. The nature and severity of the changes are dose dependent. A pilot study in 2 young normal BMI children showed EEG changes in both subjects after 2 drops of cyclopentolate 1% and no changes after no drops. Most of the children receiving cyclopentolate are young. There is evidence that BMI distribution is shifting

towards outer limits. The purpose of this study is to gain more insight in the presence and nature of CNS changes after cyclopentolate. A scientific base is present and EEG recording is proven to be a sensitive method to demonstrate these changes.

Amendement
Because of the presence of sinus rhythm changes in 3 of the 5 included subjects, this study is extended with an ECG. A scientific base is present.
The purpose of the ECG assessment is to gain insight in the presence and nature of ECG changes after cyclopentolate.

Study objective

To compare the EEG pattern after administration of cyclopentolate with the EEG pattern after placebo eye-drops.

Primary outcome
EEG pattern changes after administration of two drops of cyclopentolate1% compared with placebo.

Secondary outcomes
- Pattern changes EEG
- Time of onset of EEG changes
- Frequency of EEG changes
- Factors (e.g. age, BMI etc.) that influences onset of- and/or changes in EEG pattern.

- Pattern changes ECG
- Time of onset of ECG changes

Study design

This investigator initiated study is designed as a prospective, single-centre, cross sectional, quantitative, randomized, single-blind placebo-controlled observational study.

This study investigates the presence, nature and severity of central nervus system changes with EEG recording and investigate risk factors for onset of central nervus system changes after administration of two drops of cyclopentolate 1%. The duration of the study will be approximately 12 months.

Intervention:

Randomized
• Two drops of cyclopentolate hydrochloride 1%, with an interval of 5 minutes in both eyes

or
• Placebo:

Study burden and risks

Risk and burden:
There are no additional risks present since subjects are already planned for a routine cycloplegic refractive assessment according to their treatment or standard departmental follow-up. There are no risk involved in the EEG or ECG registration nor application of the EEG or ECG electrodes. The additional application of the placebo eye-drops provide a small burden. The placebo eye-drop is very child friendly and does not sting or burn. Eventual discomfort of feeling the liquid in the eye is of a very short duration. Inconvenience will mainly consist of the additional visit, the limitation of staying on a bed for 50 minutes and extra washing hair after each EEG recording.

Benefit and group relatedness:
The results will lead to insight in the onset, nature and extensiveness of central changes due to cycloplegics. Factors involved in the onset of central adverse events will be determined. Results can be extrapolated to the general population and will be translated to an optimal method e.g. intervention for obtaining objective refraction in children.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Healthy 6 to 16 year old volunteers, requiring an objective refraction because of standard departmental protocol, without syndromes or diseases or behaviour and/or attention syndromes (e.g. ADHD or ADD or autism spectral conditions etc.) and possessing a normal or low BMI. ;High BMI is defined in girls as having a BMI higher than 17.33 at 6 years of age, 17.74 at 7 years of age, 18.34 at 8 years of age, 19.06 at 9 years of age, 19.85 at 10 years of age, 20.73 at 11 years of age, 21.67 at 12 years of age, 22.57 at 13 years of age, 23.33 at 14 years of age, 23.93 at 15 years of age en 24.36 at 16 years of age (see page 27 of the protocol). For boys high BMI is defines as having a BMI higher than 17.54 at 6 years of age, 17.91 at 7 years of age, 18.43 at 8 years of age, 19.09 at 9 years of age, 19.83 at 10 years of age, 20.54 at 11 years of age, 21.21 at 12 years of age, 22.90 at 13 years of age, 22.61 at 14 years of age, 23.28 at 15 years of age en 23.89 at 16 years of age (see page 27 of the protocol).;Low BMI is defined in girls as having a BMI lower than 13.93 at 6 years of age, 14.01 at 7 years of age, 14.17 at 8 years of age, 14.43 at 9 years of age, 14.78 at 10 years of age, 15.26 at 11 years of age, 15.84 at 12 years of age, 16.44 at 13 years of age, 17.02 at 14 years of age, 17.53 at 15 years of age en 17.96 at 16 years of age (see page 27 of the protocol). For boys, low BMI is defined as having a BMI lower than 14.04 at 6 years of age, 14.07 at 7 years of age, 14.21 at 8 years of age, 14.42 at 9 years of age, 14.70 at 10 years of age, 15.04 at 11 years of age, 15.48 at 12 years of age, 15.99 at 13 years of age, 16.55 at 14 years of age, 17.14 at 15 years of age en 17.71 at 16 years of age (see page 27 of the protocol).

Exclusion criteria

All subjects that do not meet the inclusion criteria described in D4a

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-07-2012
Enrollment:	24
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	unit dose® cyclopentolate hydrochloride 1%; 10 mg/ml
Generic name:	cyclopentolate hydrochloride 1%; 10 mg/ml
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	11-05-2012
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	16-05-2012
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO
Date: 19-06-2012

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO
Date: 13-09-2012

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO
Date: 28-09-2012

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO
Date: 17-12-2014

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO
Date: 15-01-2016

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 25564
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2012-001149-42-NL
CCMO	NL35009.098.12
OMON	NL-OMON25564