EEG veranderingen bij kinderen door cyclopentolaat oogdruppels.

Gepubliceerd: 22-05-2012 Laatst bijgewerkt: 15-05-2024

Primary outcome: There will be a changes in EEG pattern after apllication of cyclopentolate compared to the EEG pattern after administraion of placebo eyedrops. Secondary outcome: There will be a difference in chnage of the EEG pattern between...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON25564

Bron
Nationaal Trial Register

Verkorte titel
Cycloplegic EEG

Aandoening

Central Nervous System (CNS) changes
EEG pattern changes

Ondersteuning

Primaire sponsor: Medical Centre Haaglanden
Medisch Centrum Haaglanden
Overige ondersteuning: Medical Centre Haaglanden
Medisch Centrum Haaglanden

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Aims:
1. To investigate changes in EEG pattern after cyclopentolate 1% eye-drops;
2. To indentify which pattern changes;
3. To investigate the rate/depth/seriousness of change(s);
4. To investigate the time of onset of change(s);
5. To investigate whether age (category) influences onset of- and/or changes in EEG pattern;
6. To investigate whether low BMI influences onset of- and/or changes in EEG pattern;
7. To investigate whether subjective changes in behaviour, physical or mental state can be observed;
8. To investigate whether subjects observe changes in their physical or mental state.

Amendement:
9. To investigate changes in ECG pattern after cyclopentolate 1% eye-drops;
11. To investigate changes in sinus-rhythm;
10. To investigate the time of onset of sinus-rhythm and ECG change(s).

Objectives:
To compare EEG pattern after cycloplegics with EEG patterns after placebo eye-drops.

Primary outcome:
Detect if changes in EEG pattern are present after administration of a double dose of cyclopentolate 1%.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

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 are 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:
Following the first 5 study subjects, the results of these subjects were evaluated. Three out of five showed significant changes in hart-rate. Both tachycardia and bradycardia is reported as a rarely but possible side effect after anticholingergics. However no detailed scientific literature of changes after cyclopentolate is present. As a result of the findings in 3 subjects an elaborated (12 channel) ECG recording will be performed in all study subjects from now on included in this study. The ECG recording will be performed for 1) patient safety reasons and for 2) research purposes. A scientific base is
present. Furthermore blood-pressure will be monitored.

Objective:

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

Primary outcome:

Detect if changes in EEG pattern are present after 2 drops of cyclopentolate 1% compared to placebo eye-drops.

Secondary outcomes:

1. Detection which pattern changes;

2. Detection of time of onset of EEG pattern changes;

3. Detection of the amount and depth of EEG pattern change;

4. Detection of factors (e.g. age, BMI etc.) which influences onset of- and/or changes in EEG pattern.

Study design:

A prospective, single-centre, cross sectional, quantitative, randomized single-blind placebo-controlled observational study.

Study population:

Healthy 6 to 16 year old volunteers, requiring an objective refraction because of standard

departmental protocol, not having syndromes or diseases or behaviour or attention syndromes and having a normal or low BMI.

Intervention:

2 visits with EEG recording. Randomized; one visit 2 drops of cyclopentolate 1%; interval 5 minutes and 1 visit placebo; 2 drops; interval 5 minutes.

Main study parameters/endpoints:

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

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.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

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/ECG registration nor application of the EEG/ECG electrodes or blood-pressure measurements. 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 consists of the additional visit, the limitation of sitting on a bed for 1 hour 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 cyclopentolate. 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.

Doel van het onderzoek

Primary outcome:

There will be a changes in EEG pattern after apllication of cyclopentolate compared to the EEG pattern after administraion of placebo eyedrops.

Secondary outcome:

There will be a difference in chnage of the EEG pattern between normal an low BMI subjects.

EEG changes will be more profound in younger than in older children.

Amendement:

There will be a difference in sinus-rhythm and/or ECG pattern after administration of cyclopentolate compared to placebo eyedrops.

There will be a difference in change of sinus- rhythm between normal and low BMI subjects.

Sinus-rhythm and/or ECG changes will be more profound in younger than older children.

Onderzoeksopzet

Both visits:

After the introduction the technician of the department Neurophysiology will place the electrodes on the skull of the child. During this the child can watch television or read a comic book. A 12 channel ECG electrode attachment will be conducted. After completing the EEG electrode attachment a 10 minute base recording will be performed.

The conducting researcher will take a numbered envelop, according to consecutive number of the subject, containing the randomization sequence. The eye-drops will be administered by the CR according to the designated sequence and according to protocol.

The EEG/ECG registration will take place in the 50 minutes following administration of the eye drops.
At 50 minutes retinoscopy and fundoscopy will be performed by the Conducting Researcher. A second bloodpressure measurement will be conducted. Treatment arrangements will be noted in the outward patient chart and discussed with child and parent(s) and/or guardian(s). Thereafter the EEG electrodes will be removed.

Neurophysiologist:

The neurophysiologist, who is blinded, will adjudicate the EEG registrations afterwards. All EEG registrations will be judged by the same neurophysiologist, to prevent an inter-observer

bias.

Any changes in EEG patterns will be noted and described.

Amendement:

Cardiologist:

The cardiologist, who is blinded, will adjudicate the ECG registrations afterwards. All ECG registrations will be judged by the same cardiologist, to prevent an inter-observer bias.

Any changes in ECG patterns will be noted and described.

Onderzoeksproduct en/of interventie

Randomized:

1. Two drops of cyclopentolate hydrochloride 1%, with an interval of 5 minutes in both eyes or;

2. Placebo: Two drops of saline 0.9%, with an interval of 5 minutes in both eyes.

The randomizations will not be known to the EEG evaluating neurophysiologist, so that a single blind character is obtained.

This design is not double blinded. The participating subjects will be blinded for the first 15 minutes. Thereafter blinding will be broken due to a certain amount of blurred vision after cyclopentolate and normal vision after placebo

The randomization will be broken at the end of the study. The endpoint of study is defined as the moment all the measurements and EEG reviews have been done, all these data are admitted in SPSS database and the database is closed.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

A patient is considered for the study when:

1. Requiring an objective refraction because of standard departmental protocol;

2. Having good general health;

3. Not having syndromes or diseases or disorders in behaviour or attention (e.g. ADHD or ADD or autism like conditions etc.);

4. Aged 6 to 16 years;

5. Having a normal or low BMI.

To avoid selection bias the recruiters must offer participation to all eligible patients.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

All subjects that do not meet the inclusion criteria.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	29-05-2012
Aantal proefpersonen:	24
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	22-05-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 41638
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3278
NTR-old	NTR3446
CCMO	NL35009.098.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON41638

Resultaten

Samenvatting resultaten
N/A