Feasibility of neurocognitive testing in healthy children

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The primary objective is (1) to establish the feasibility of using these neurocognitive tasks in children, and (2) to establish intra-individual variance of task results upon test repetition.The secondary objective is to assess how children have...

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

Summary

ID

NL-OMON31940

Source
ToetsingOnline

Brief title
Feasibility of neurocognitive testing in healthy children

Condition

- Other condition

Synonym
none

Health condition

De gebruikte neurocognitieve testen zijn bruikbaar als biomarker voor centrale effecten van geneesmiddelen in bredere zin. Bij deze pilot is er geen sprake van een specifieke aandoening die bestudeerd wordt.

Research involving
Human

Sponsors and support

Primary sponsor: Centre for Human Drug Research
Source(s) of monetary or material Support: Eigen middelen van de verrichter

Intervention

Keyword: Child, Neuropsychological Tests, Pilot study

Outcome measures

Primary outcome

Results of Neurocognitive tasks:

- Stroop color-word task

- Adaptive tracking

- Smooth eye pursuit

- Saccadic Eye movements

- Finger tapping

- Body sway

Results of a short questionnaire taken after completion of the Neurocognitive

tasks.

Secondary outcome

NA

Study description

Background summary

Neurocognitive tasks are frequently employed in scientific research. Task

results can be used as correlates of disease state, are often used by neuropsychologists to elucidate the pathogenesis of neuropsychologic disorders and can serve as biomarker of drug effects.

Development and use of such biomarkers in pediatric populations lags behind when compared to the adult population. The need for validated biomarkers in pediatric drug research is substantial in the light of an expected intensification of pediatric drug research following the adoption of EU regulation No. 1901/2006.

The Centre for Human Drug Research (Leiden, the Netherlands) has extensive experience with a test battery called the Neurocart. The Neurocart consists of a selected set of neurocognitive tasks, the results of which are used as a biomarker cq trial endpoint in early phase drug research in adults. It is reasonable to expect that tasks incorporated in this test battery are also suited for use in the pediatric population to detect drug effects and/or discriminate between disease states.

Study objective

The primary objective is (1) to establish the feasibility of using these neurocognitive tasks in children, and (2) to establish intra-individual variance of task results upon test repetition.

The secondary objective is to assess how children have experienced trial participation.

Study design

Observational cohort study

Study burden and risks

This study does not entail any known risks.

The burden imposed by the study is mainly the time investment needed for travel and test performance. Study occasions will be planned in such a way, that they do not interfere with school attendance. One of the tasks involves the application of 3 electrodes in order to measure eye movements. These electrodes are comparable to ecg stickers, and application or removal is not painful.

In our opinion the study meets the legal requirement of negligible risk and minimal burden.

There is no benefit associated with study participation (i.e. non-therapeutic study)

The proposed study can only be performed in the group of paediatric patients as described above. Performing this study in an adult population would yield major difficulties since results on neurocognitive tasks can be expected to develop with age. This phenomenon was demonstrated in a developmental study of visuospatial attention. In addition, we want to establish how children have experienced study participation. The study objectives thus cannot be met by performing the study in legally competent adults.

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

•Age 8-12 years
•Written informed consent from parents having parental responsibility or from the legal

guardian. In the case of a child aged 12 years or older the written informed consent of the child is needed in addition to that of parents having responsibility/legal guardian, in the case of a child aged younger than 12 years, assent needs to be provided.

Exclusion criteria

•Any known psychiatric diagnosis (e.g. autism, oppositional defiant disorder, ADHD)
•Dyslexia
•Learning disability
•Significant behavioural problems
•Use of medication
•Preterm birth

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	20-10-2007
Enrollment:	16
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL19763.058.07