Prognostic factors for neurocognitive functioning and outcome after mild traumatic brain injury in children aged 8 and older

Published: 22-03-2010
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First objective is to indicate neurocognitive outcome after mild traumatic brain injury in children. Second objective is to indicate prognostic factors for negative neurocognitive outcome.

Ethical review	Not approved
Status	Will not start
Health condition type	Cranial nerve disorders (excl neoplasms)
Study type	Observational non invasive

Summary

ID

NL-OMON35711

Source
ToetsingOnline

Brief title
Neurocognitive functioning after mild TBI in children

Condition

- Cranial nerve disorders (excl neoplasms)

Synonym
traumatic brain injury-concussion

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Ziekenhuis Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W,Momenteel loopt een aanvraag bij de Hersenstichting Nederland

Intervention

Keyword: cohort, neurocognitive, outcome, TBI

Outcome measures

Primary outcome

Screening Tool for Cognitive, emotional and social consequences of traumatic

brain injury in children.

Secondary outcome

Neurocognitive functioning: neuropsychological tests, school performance and

professional care needed.

Study description

Background summary

Each year 12.00 children are admitted to the hospital due to a mild brain injury. The term mild has the connotation that the consequence are minimal, however this is probably not true as 10% of these children have stil problems on the longterm. It is stil unknown which children are at risk for longterm consequences. In this study we want to identify risk factors for long term consequence of mild traumatic brain injury in children.

Study objective

First objective is to indicate neurocognitive outcome after mild traumatic brain injury in children. Second objective is to indicate prognostic factors for negative neurocognitive outcome.

Study design

A longitudinal, prognostic study

Study burden and risks

The burden of this study is minimal. The neuropsychological assessment takes 90 minutes and based on experience we can conclude that children like to perform these tasks. Parents and teachers fill in questionnaires, which takes 15 minutes.

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

1) Age between 8-16 years
2) mild traumatic brain injury
3) normal understanding Dutch language
4) at least a mean level of intelligence
5) informed consent parents

Exclusion criteria

1) Other neurological or psychiatric deficits
2) cause of brein inury is physical abuse

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	510
Type:	Anticipated

Ethics review

Not approved

Date:	22-03-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL25049.068.08