Pediatric mild traumatic head injury: risk factors for long term effects

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Primary goal:To provide an overview of long term effects (neurocognitive, behavioral and learning problems) in children with MTHI and to identify specific risk groups with a higher prevalence of more serious problems. This knowledge can contribute...

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

Summary

ID

NL-OMON46361

Source
ToetsingOnline

Brief title
Long term effects of pediatric mild traumatic head injuries

Condition

- Other condition

Synonym
mild traumatisch head injury; head injury

Health condition

Neurologisch/traumatisch hersenletsel

Research involving
Human

Sponsors and support

Primary sponsor: Spaarne Gasthuis
Source(s) of monetary or material Support: Subsidies (zelf geïniteerd;dus alternatieve stroom)

Intervention

Keyword: Long term effects, Mild traumatic head injury, Neuropsychology, Pediatric

Outcome measures

Primary outcome

This study targets long term effects (neurocognitive, behavioral and learning

problems) in children with MTHI. Disabilities in more or more of these domains

are the primary outcome which will be used to identify specific risk groups.

Secondary outcome

- Neurocognitive profile (disabilities in neurocognitive processes)

- Behavioral profile (reported by parents, teachers and the child itself)

- Learning problems (school results)

Study description

Background summary

Traumatic head injury (THI) is the most important cause of non congenital disabilities in children. In Dutch hospitals on average we see 85.000 patients each year with traumatic head injuries, of which 19.000 are pediatric patients. Pediatric patients with THI have a higher risk of neurocognitive, behavioral and learning problems. These problems can threaten the further development of the young child.
Approximately 90% of all THIs is a mild traumatic head injury (MTHI). MTHI is defined as trauma to the head, except for superficial trauma of the face. By definition the trauma was caused by acceleration-deceleration trauma to the head. To diagnose MTHI the following criteria were applied, 1) Glasgow Coma Scale score of 13-15 at first examination at the emergency department, 2) maximum duration of post traumatic loss of consciousness of 30 minutes, 3)

maximum duration of post traumatic amnesia of 24 hours.
Literature shows us that MTHI is followed by total recovery of initial symptoms within several months. However, current literature is also characterized by a high heterogeneity in outcomes in children with MTHI. Recent studies suggests that specific risk groups exist that have a higher risk for permanent impact on neurocognitive and behavioral functioning after MTHI. It is of great importance to identify these high risk groups and to better predict their long term outcomes. With that we can adjust the individual need of care of these children and their families.

This study is a follow up study on a large multicenter prospective observational cohort study of pediatric patients admitted to the emergency department with a MTHI. Data of more than a thousand children were collected in six community hospitals in The Netherlands between 1 April 2015 and 31 December 2016. The aim of this follow up study is to better predict long term effects (neurocognitive, behavioral and learning problems) in children with MTHI. Our goal is to identify specific high risk groups and thereby to better understand how these problems can exist.

Study objective

Primary goal:
To provide an overview of long term effects (neurocognitive, behavioral and learning problems) in children with MTHI and to identify specific risk groups with a higher prevalence of more serious problems. This knowledge can contribute to the accuracy of the prognosis in children with MTHI.

Secondary goal:
To understand the link between demographics, clinical predictors and long term effects. Exploratory research will focus on the coherence in limitations in different domains. Thereby, we can investigate in in what way specific neurocognitive impairments can contribute to daily life problems.
This knowledge will contribute to the understanding of long term problems and give way to targeted interventions.

Study design

This study is a observational follow up study on a large multicenter prospective observational cohort study of pediatric patients admitted to the emergency department with a MTHI. Data of more than a thousand children were collected in six community hospitals in The Netherlands between 1 April 2015 and 31 December 2016.

We will contact all eligible parents and/or children by email. After a two weeks notice we will contact them by phone. If eligible participants want to

participate we will arrange a test session in one of the community hospitals by choice. During this 2 hour session the child will conduct a computerized and standardized neurocognitive test under supervision of trained neuropsychology students. Besides that we ask permission to retrieve school results and both child and parents receive a standardized questionnaire on their functioning and prehistory.

Data on demographics, traumamechanism, major and minor criteria according to the current national guidelines, available radiography and clinical course during possible observation, are already collected and categorized in an electronic database (Research Manager). These data will be completed with information on prehistory since trauma, neurocognitive testing, school results and the questionnairet.

Study burden and risks

To our opinions there are no specific risks. Smaller previous studies show that children are eager to do the neurocognitive tests and that they enjoy them. Besides a two hour time investment we see no other burden.

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

This is a follow up study from a cohort included between April 2015 and December 2016. All pediatric patients (aged 0-18 years) admitted to the emergency department with a mild traumatic head injury were eligible for inclusion. MTHI was defined as trauma to the head, except for superficial trauma of the face. By definition the trauma was caused by acceleration-deceleration trauma to the head. To diagnose MTHI the following criteria were applied, 1) Glasgow Coma Scale score of 13-15 at first examination at the emergency department, 2) maximum duration of post traumatic loss of consciousness of 30 minutes, 3) maximum duration of post traumatic amnesia of 24 hours.
A the time of follow up patients should be aged 6-18 years. During the initial inclusion at the emergency department their parents should have consented that we could approach them later for possible follow up studies.

Exclusion criteria

Children aged less than six years or 18 years and older.
Severe developmental delay.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-10-2018
Enrollment:	263
Type:	Actual

Ethics review

Approved WMO Date:	09-08-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-09-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-05-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL65415.029.18