PErsonalized PRognosis for Children with Traumatic Brain Injury

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21973

Source
NTR

Brief title
PEPR

Health condition

Children with Traumatic Brain Injury

Sponsors and support

Primary sponsor: Amsterdam UMC, location AMC
Source(s) of monetary or material Support: Amsterdam UMC, location AMC

Intervention

Outcome measures

Primary outcome

Motor functioning, neurocognitive functioning and behavioral functioning will be used to construct the overall outcome score

Secondary outcome

Brain structure and function, health status, school functioning, specific neurocognitive functioning, quality of life

Study description

Background summary

Outcome prediction in children with TBI falls short, preventing clinicians to tailor medical decision making to the child’s individual risk profile. This contributes to overtreatment (i.e. unnecessary follow-up) and undertreatment (i.e. undetected impairment). We aim to develop an innovative personalized prognostic model for outcome of children with TBI, using a unique combination of demographic, pre-injury and clinical predictors. The value of innovative MRI techniques and promising machine learning algorithms will be investigated for prognostic purposes that can be clinically implemented.

Study objective

To develop an innovative personalized prognostic model for outcome of pediatric TBI in crucial domains of child development (i.e. motor, neurocognitive, and, behavioral functioning), using a unique combination of demographic, pre-injury and clinical predictors. The prognostic model can importantly contribute to the planning of early rehabilitation and follow-up, preventing unnecessary care for children with good recovery and facilitating swift and adequate monitoring and treatment of children with high-risks of adverse outcome.

Study design

T0; hospital admission (demographic predictors, pre-injury predictors, clincial predictors)
T1; 1 month post-injury only for children aged 8 years and older (brain strucuture and function assessed with MRI)
T2; 6 months post-injury (motor, neurocognitive, and school functioning as well as brain function assessed with EEG)

Contacts

Public
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Scientific
Amsterdam UMC, location AMC

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Eligibility criteria

Inclusion criteria

1. 4-18 years;
2. Fluent Dutch speaker;
3. Inhabitant of The Netherlands;
4. Hospital admission for mild to severe TBI.
5. No documented and/or parent-reported diagnosis of a neurological disorder (other than TBI).

Exclusion criteria

1. Absence or withdrawal of written informed consent;
2. Severe motor disability that interferes with outcome assessment at time of assessment;
3. Inability to comprehend testing instructions at time of assessment;
4. Somatic disorders unrelated to TBI and possibly affecting the outcome assessments at time of assessment.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	01-12-2020
Enrollment:	210
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion
Date: 16-11-2020

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 54521
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9051
CCMO	NL71283.018.19
OMON	NL-OMON54521

Study results