PErsonalized PRognosis for Children with Traumatic Brain Injury

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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...

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

Samenvatting

ID

NL-OMON21973

Bron
NTR

Verkorte titel
PEPR

Aandoening

Children with Traumatic Brain Injury

Ondersteuning

Primaire sponsor: Amsterdam UMC, location AMC
Overige ondersteuning: Amsterdam UMC, location AMC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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)

Contactpersonen

Publiek

Amsterdam UMC, location AMC
Cece Kooper

0657571421

Wetenschappelijk

Amsterdam UMC, location AMC
Cece Kooper

0657571421

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland
Status: Werving gestart

(Verwachte) startdatum:	01-12-2020
Aantal proefpersonen:	210
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	16-11-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 54521
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten