Acute Injury Markers in mTBI

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

Samenvatting

ID

NL-OMON24795

Bron
Nationaal Trial Register

Verkorte titel
AIM-TBI

Aandoening

mild traumatic brain injury

Betreft onderzoek met
Mensen

Ondersteuning

Primaire sponsor: UMCG
Overige ondersteuning: UMCG (Mandema committee)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

• Glasgow Outcome Scale Extended (GOSE) at 6 months post-injury (Jennett et al. 1981). This questionnaire is validated. • Post-traumatic complaints (measured using the head injury

symptom checklist (HISC) at 6 months post-injury (de Koning et al. 2016)). This questionnaire is validated.

Toelichting onderzoek

Achtergrond van het onderzoek

Mild traumatic brain injury (mTBI) is the most common neurologic disorder. One out of 4 patients develops long-lasting cognitive and emotional complaints that interfere with daily functioning. Therefore, mTBI poses a significant public health burden. Over the years multifactorial models have been developed, which aid in the prediction of outcome after mTBI. It has been shown that in addition to acute injury related factors, such as loss of consciousness and amnesia, outcome is strongly influenced by pre-existent psychological factors, for instance coping style and emotion regulation. Despite these scientific efforts, persistent complaints are still rather unpredictable in individual patients, for whom injury mechanisms are often comparable. So far, little is known about the influence of physiological effects of the injury, such as cellular injury, neuroinflammation, and acute stress, on outcome after mTBI. Previous functional MRI (fMRI) research has demonstrated that persistent complaints after mTBI are related to alterations in neural networks. Therefore, a pivotal question is whether acute physiological effects lead to disturbances in neural networks that are important for emotion regulation, and if there is an interaction with pre-existent personality, coping style, and stress levels, This topic has never been touched upon, and therefore forms a gap in mTBI research. With the current study, we aim to conduct biochemical, psychometric and MRI-experiments in order to disentangle the interaction(s) between (acute) physiological and (long-term) psychological consequences of TBI. Hopefully, this will lead to a better understanding of the etiology of persistent complaints and poor outcome, and to starting points for the development of tailored pharmacological and/or psychological treatments for patients with mTBI.

Doel van het onderzoek

Primary Objective: • To investigate whether or not persistent complaints and poor outcome after mTBI be explained by an interaction between physiological and psychological factors. In other words, the aim is to investigate whether a more optimal model based on a combination of abovementioned factors can be developed, in comparison to models based on either physiological or psychological factors. Secondary Objective(s): • To identify specific patterns of brain specific protein, cortisol and cytokine release and HRV, as markers of acute brain damage or alteration of physiological processes in patients with mTBI. • To determine if patients with mTBI differ in cortisol and cytokine release from patients with another stressful condition (i.e. orthopedic injury), and healthy controls. • To find possible relationships between acute physiological disturbances (inflammation, stress) and altered activity/connectivity of neural networks in mTBI, and to determine whether or not this is related to psychological factors.

Onderzoeksopzet

4

Contactpersonen

Publiek

UMCG
Harm Jan Van der Horn

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Wetenschappelijk

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Deelname eisen

Leeftijd
Volwassenen (18-64 jaar)
Volwassenen (18-64 jaar)
65 jaar en ouder
65 jaar en ouder

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients with mild traumatic brain injury (mTBI) must be aged 18 years or older. Mild TBI is defined by a Glasgow Coma Scale score of 13-15 and loss of consciousness ≤ 30 minutes and/or post-traumatic amnesia < 24 hours (Kayd et al. 1993). Inclusion criteria for the orthopedic control group are: age 18 years or older, and sustaining a minor injury to an extremity (e.g. sprain or uncomplicated fracture of wrist or ankle. For the healthy control group: age 18 years or older.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion criteria: neurological or psychiatric co-morbidity, admission for prior TBI, drug or alcohol abuse, and mental retardation, language barriers or illiteracy, prohibiting understanding and completion of questionnaires. For the MRI-study: implanted ferromagnetic devices or objects, pregnancy or claustrophobia.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Historische controle groep
Doel:	Algemeen wetenschappelijk

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	17-01-2020
Aantal proefpersonen:	700
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	07-07-2020
Soort:	Eerste indiening
Toetsingscommissie:	METC NedMec

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8484
Ander register	METc UMCG : METc 2018/681

Resultaten