Acute Injury Markers in mTBI

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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...

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

Summary

ID

NL-OMON24795

Source
NTR

Brief title
AIM-TBI

Health condition

mild traumatic brain injury

Research involving
Human

Sponsors and support

Primary sponsor: UMCG
Source(s) of monetary or material Support: UMCG (Mandema committee)

Intervention

Outcome measures

Primary outcome

• 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.

Secondary outcome

Emergency department: • Blood cytokine levels. • Blood biomarker levels (proteins of cell injury). • Salivary cortisol levels. • Heartrate variability. Two weeks post-injury: • HISC at 2 weeks post-injury. • Anxiety/depression at 2 weeks post-injury (Hospital Anxiety and Depression Scale (HADS) (Zigmond and Snaith 1983)). This questionnaire is validated. • Coping (Utrechtse Coping List (UCL) at 2 weeks post-injury(Schreurs et al. 1988)). This questionnaire is validated. • Personality characteristics (Big Five Inventory (BFI) at 2 weeks post-injury (Goldberg 1993)). This questionnaire is validated. Four weeks post-injury • Blood cytokine levels. • Hair cortisol levels. • Brain network connectivity.

Study description

Background summary

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.

Study objective

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.

Study design

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Contacts

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Eligibility criteria

Age
Adults (18-64 years)
Adults (18-64 years)
Elderly (65 years and older)
Elderly (65 years and older)

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-01-2020
Enrollment:	700
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	07-07-2020
Application type:	First submission
Review commission:	METC NedMec

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
NTR-new	NL8484
Other	METc UMCG : METc 2018/681

Study results