Frontal cerebral hemodynamic changes in adults after mild traumatic brain injury using Functional NearInfrared Spectroscopy (fNIRS); a pilot study.

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

Summary

ID

NL-OMON45790

Source
ToetsingOnline

Brief title
fNIRS in adults after mild traumatic brain injury.

Condition

- Other condition

Synonym
Mild traumatic brain injury - concussion

Health condition

(Licht) traumatisch hersenletsel

Research involving

Human

Sponsors and support

Primary sponsor: UMC Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: adults, fNIRS, mild traumatic brain injury, outcome

Outcome measures

Primary outcome

Primary outcome measures:

a) (Changes in) frontal cerebral perfusion measured using fNIRS (including

cognitive tasks) in patients compared to healthy controls.

b) Functional outcome three months post-injury, determined using the Glasgow

Outcome Scale Extended (GOSE).

Secondary outcome

Secondary outcome measures:

a) Functional outcome six weeks post-injury, determined using the Glasgow

Outcome Scale Extended (GOSE).

b) Post-traumatic complaints two weeks and three months post-injury determined

using the *Groningen Klachtenlijst*.

Study description

Background summary

Traumatic brain injury (TBI) is one of the most frequent neurological disorders worldwide. Approximately 80.000 persons with traumatic brain injurer admitted to the Emergency Department in the Netherlands. The patients differ widely

concerning age, trauma mechanism, injury severity, course and eventual recovery. Based on clinical criteria mild, moderate and severe TBI are distinguished; the majority consists of mild TBI (80-85%). In patients with mild TBI posttraumatic signs and symptoms can be present, both physical as cognitive, that may prolong and have a great impact on daily life, for instance on return to school or study and/or work.

Next to physical examination, radiological investigations are used to determine injury severity in patients with mild TBI. In the acute phase especially computed tomography (CT) scanning is used. However, in a large majority (85-90%) of mild TBI patients no structural traumatic abnormalities are found using CT scanning. In adult mild TBI patients changes in cerebral perfusion were demonstrated using hemodynamic imaging techniques like the perfusion CT-scan, whereas the regular CT-scan didn*t show any abnormalities. A decrease in frontal cerebral blood flow was found that was associated with outcome six months post-injury. Still, the perfusion CT-scan is time consuming and labour intensive with additional radiation exposure.

By means of Functional Infrared Spectroscopy (fNIRS) it is possible to detect and monitor cerebral hemodynamics non-invasively and without X-ray exposure. Cerebral activity will result in an increase in oxygen use, leading to an increase in cerebral blood flow through the so called *neurovascular coupling*. This in turn will result in changes in tissue oxyhaemoglobin and de-oxyhaemoglobin, which can be detected with fNIRS. Especially the frontal lobes can be visualized using fNIRS. Considering the fact that fNIRS is relatively easy to use and there is no radiation exposure, it is very much suited to evaluate the cerebral hemodynamics, specifically in the acute setting post-injury. Furthermore, fNIRS can be combined with attention and memory tasks to get an impression of post-traumatic cognitive functioning in relation to hemodynamic changes in the frontal cerebral areas.

Study objective

In adult TBI patients no data is available on the feasibility of fNIRS in combination with cognitive tasks, particularly in the acute phase post-injury at the emergency department. The further aim of this study is to investigate the potential of fNIRS as a screening tool in the acute phase to select patients at risk for suboptimal recovery.

The goals of this study are therefore threefold:
1. Evaluation of the feasibility of fNIRS (including cognitive tasks) in adult mild TBI patients during the acute phase.
2. Collecting fNIRS normal values (including cognitive tasks) in healthy adult control subjects.
3. Examining the relation between frontal cerebral perfusion abnormalities and outcome.

Study design

Within predetermined time windows all adult mild TBI patients will be approached to participate in this study. Naturally, the treating physician will be consulted. If the patient gives consent, he/she will be asked to complete the first questionnaire followed by the fNIRS measurement (including cognitive tasks).
Two weeks and three months post-injury/ after the emergency department visit participating patients will be send two questionnaires by e-mail or regular mail (the patient will be given the ability to chose from both options) to complete and subsequently to return. When no response from the patient is received, he/she will be contacted by e-mail and/or phone again as reminder.

Study burden and risks

fNIRS analysis encompasses no risks worth mentioning and we consider the time investment asked acceptable. fNIRS is non-invasive.

The fNIRS measurement and completion of the first questionnaire will be performed directly following the ED visit, which will therefore be somewhat lengthened. The remaining two questionnaires can be completed at home (two times) and subsequently returned by regular mail or even e-mail.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Traumatic brain injury
Glasgow Coma Scale score 13-15 at Emergency Department admittance
Age 18 years and older
Recovered from posttraumatic amnesia (PTA)
Informed consent by patient

Exclusion criteria

No permanent residence
Intoxication with or addiction to alcohol and/or drugs
Previous admission for traumatic brain injury
Psychiatric illness including depression
Epilepsia
Severe hypoxia, hypercapnia or anemia
Neurodegenerative disease
No comprehension of Dutch language

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:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-07-2019
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	13-07-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL61599.042.17