Diffuse axonal injury in moderate to severe TBI patients: prognostic factors and impact on neural network integrity

Published: 08-07-2015
Last updated: 19-04-2024

The primary objective is to study the relationship between DAI lesions on conventional MRI, clinical parameters and prognosis. As secondary objective is the additive value of more advanced MR Imaging in which white matter tracts are analysed (as...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Injuries NEC
Study type	Observational non invasive

Summary

ID

NL-OMON47025

Source
ToetsingOnline

Brief title
Diffuse axonal injury in moderate to severe TBI patients

Condition

- Injuries NEC
- Structural brain disorders

Synonym
Diffuse Axonal Injury en Traumatic Brain Injury

Research involving
Human

Sponsors and support

Primary sponsor: Sint Elisabeth Ziekenhuis
Source(s) of monetary or material Support: ZonMW Topzorg Project

Intervention

Keyword: DAI, prognosis, TBI

Outcome measures

Primary outcome

The clinical outcome measured by the Glasgow Outcome Scale- Extended (GOS-E) at

12 months is the primary outcome in this study.

Secondary outcome

The secondary study parameters are

* Health related Quality of Life (QOLIBRI) at 6 and 12 months

* GOS-E at discharge, 6 and 12 months

* IQCODE as filled out by a relative or other informant of the subject

* CNS Vital Signs at 12 months

* Anxiety and depression measured with HADS score at 12 months

Study description

Background summary

Traumatic brain injury (TBI) causes different primary lesions, such as intracranial hematomas, cortical contusions as well as diffuse axonal injury (DAI). DAI is typically identified on T2* or SWI MRI scans and frequently present in severe TBI patients.
The axonal injury results from the stretching and deformation of the brain tissue caused by acceleration-deceleration forces.
DAI can be graded in 3 categories (1 to 3). Whereas stage 3 is often associated with a poor outcome, the outcome in stage 1 and stage 2 shows conflicting results. Furthermore, DAI abnormalities seem to have a predilection for certain brain locations (cerebral white matter, corpus callosum and rostral brainstem). These DAI lesions probably cause a disruption in local neural networks but the long-term effect on cognitive functions is unclear. It is expected that a higher number of DAI and/or DTI lesions result in more cognitive deficits.

Study objective

The primary objective is to study the relationship between DAI lesions on conventional MRI, clinical parameters and prognosis.
As secondary objective is the additive value of more advanced MR Imaging in which white matter tracts are analysed (as measured using diffusion tensor imaging (DTI)) to predict long term functional outcome and cognitive dysfunction in patients with DAI.

Study design

This will be a prospective observational study in four level 1 trauma centres (Tilburg, Groningen, The Hague and Enschede).

Study burden and risks

There is no associated risk for participating patients. The observational character of this study allows supervising doctors to provide best care. An MRI-scan is part of standard care in this patient group. The performing of a DWI with Diffusion tensor Imaging processing is not part of standard care, but will be performed at the same time as the standard MRI-scan. Therefore there is no extra risk or burden. This extra MRI sequence will not be performed on participants in the MCH.
The GOSE at discharge means no extra burden for the patient. The GOSE at 6 months will be conducted by a telephone interview and will take 5 minutes. The GOSE measured at 6 months will be combined with a standard outpatient clinic visit or the CNS Vital Signs.
The QOLIBRI is a short questionnaire, which takes 7-10 minutes to complete. (von Steinbuechel, et al., 2012). This questionnaire can be fulfilled during an outpatient clinic visit, online via a link sent by e-mail or can be sent by posting.
The HADS questionnaire consist 14 questions, which takes 5-10 minutes to complete. This questionnaire can be fulfilled during an outpatient clinic visit, online via a link sent by e-mail or can be sent by posting.
The CNS Vital Signs (30 minutes) is a computerized set of neuropsychological tests. The patient will have to perform the CNS Vitals in the hospital. The IQCODE will be fulfilled by a family member or caretaker (10 minutes).
These measurements altogether have a minimal burden for the patient and his/her caretaker. The results can have valuable conclusions for the treatment of the individual patients and subsequently can be used in deciding to consult extra caretakers, for example a psychologist in case of depressive symptoms or a rehabilitation physician in case of cognitive dysfunction.

Contacts

Public
Sint Elisabeth Ziekenhuis

Hilvarenbeeksweg 60
Tilburg 5022GC
NL
Scientific
Sint Elisabeth Ziekenhuis

Hilvarenbeeksweg 60
Tilburg 5022GC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1) Glasgow Coma Scale Score of 3-12 after Traumatic Brain Injury, measured at trauma site or the Emergency Department
2) Diffuse Axonal Injury on MRI scan of the brain <5 months after trauma

Exclusion criteria

1) patients with clinical history of dementia or mental retardation prior to trauma,
2) patients with mass lesions > 25cc on initial CT-scan of the brain (Marshall score 5 and 6),
3) earlier hospitalization for Traumatic Brain Injury,
4) addiction to alcohol or drugs,

5) unable to attend for follow-up.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-09-2015
Enrollment:	110
Type:	Actual

Ethics review

Approved WMO

Date:	08-07-2015
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

Approved WMO

Date:	08-10-2015
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

Approved WMO

Date:	21-12-2015
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

Approved WMO

Date:	18-05-2016
Application type:	Amendment

Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	13-09-2016
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	07-12-2016
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	26-04-2018
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL53724.028.15