Markers of primary and secondary traumatic axonal injury: predictive value for acute and long-term outcome

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Project A- To find biomarkers of traumatic brain damage and to find specific biomarkers of traumatic axonal injury.Project BTo investigate the value of MRI (T1, T2*, FLAIR, SWI and DTI) in detecting traumatic axonal lesions and predicting outcome....

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

Summary

ID

NL-OMON30829

Source
ToetsingOnline

Brief title
Markers of primary and secondary traumatic axonal injury

Condition

- Other condition
- Seizures (incl subtypes)

Synonym
Brain injury caused by trauma, Traumatic Brain Injury

Health condition

traumatologische aandoeningen

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Biochemical markers and MRI, Diffuse axonal injury, Recovery and outcome, Traumatic Brain Injury

Outcome measures

Primary outcome

Project A

Blood and (if possible) CSF/micro dialysis perfusate will be collected four times a day during ICU/MCU admission to analyze the presence of primary and secondary biochemical injury markers. A CT/MRI made within 72 hours after injury will be used to assess primary focal or axonal damage. ICU registration such as hypoxia, hypotension and increased ICP are used as indications for secondary damage. The GOSE serves as the primary outcome measure.

Project B

A MRI-scan using T1, FLAIR, T2*, SWI and DTI will be performed within 3 weeks and 6 months post-injury to assess diffuse axonal lesions and focal damage. An extensive follow-up including cognitive, motor and neurological assessments at 4 weeks, 3,6 and 12 months post injury, is aimed at measuring the degree of recovery. Furthermore, a broad neuropsychological evaluation and a structural interview will be performed to evaluate behavioral/cognitive outcome at 6 months after injury.

Project C

For the genetics study, a blood sample will be collected at the Emergency

Department. The GOSE will be used as outcome measure.

Secondary outcome

not applicable

Study description

Background summary

Brain damage after head injury can be divided into primary or secondary injury and into focal damage or diffuse axonal injury (DAI). DAI is an important pathology after moderate/severe Traumatic Brain Injury (TBI) occurring in approximately 40-50% of patients and is associated with poor outcome. Due to its* microscopic nature, DAI is difficult to detect with commonly used imaging techniques such as CT. Both biochemical markers and MRI are promising tools for recognition and quantification of DAI and in this study we aim to investigate their predictive value for outcome after TBI. Furthermore, the development of DAI in relationship with cognitive and motor recovery and possible mediating effects of genetic polymorphisms will be explored.

Study objective

Project A
- To find biomarkers of traumatic brain damage and to find specific biomarkers of traumatic axonal injury.
Project B
To investigate the value of MRI (T1, T2*, FLAIR, SWI and DTI) in detecting traumatic axonal lesions and predicting outcome.
Project C
To evaluate whether polymorphisms mediate responses to environmental impact to the head and account for (a proportion of) the variability of intracranial responses upon injury.

Study design

A prospective long-term follow-up cohort study

Study burden and risks

The study only includes non-invasive procedures and risk for the patient is minimal. If participating in all elements of the study, a considerable time investment is expected from participants. The investigators will therefore try

to integrate the data collection into the standard clinical care as much as possible.

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

1. Patients who visit the emergency department with a moderate or severe TBI
2. Initial trauma occurred less than 24 hours before visiting the Emergency Department.
3. Age >= 18 years and <= 65 years

Exclusion criteria

Penetrating injury to the skull
No written informed consent by patient or proxy
History of severe neurological disease
Chronic alcohol or drug abuse
for MRI:
Metal implants other than teeth fillings
Claustrophobia

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2007
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL18113.091.07