Role of genetic polymorphisms, inflammation and biomarkers in primary and secondary traumatic brain injury

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

Summary

ID

NL-OMON31166

Source
ToetsingOnline

Brief title
Markers of traumatic brain injury and outcome

Condition

- Other condition
- Increased intracranial pressure and hydrocephalus

Synonym
braintrauma, Traumatic brain injury

Health condition

Trauma

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Biomarkers, Inflammation, Outcome, Trauma

Outcome measures

Primary outcome

Main study endpoints are genetic factors, clinical, biochemical and

inflammatory markers.

All parameters will be correlated to

- determinants of primary injury (GCS at presentation, CT-findings)

- determinants of secondary injury (hemodynamic, clinical and neurological

parameters after admission to ICU)

- MRI findings at 3 weeks and 6 months

- Outcome (as determined by the extended Glasgow Outcome Score at 6 and 12

months post injury)

- Neuropsychological testing at 3 weeks, 6 and 12 months post injury

- Parasympathetic activity (measured using heart rate variability)

Secondary outcome

Secondary objective of this study is to gain more insight in the

pathophysiological mechanisms underlying the primary impact and subsequent

ongoing cascade of events associated with secondary brain injury and

development of edema. Special attention will be given to biochemical markers of

brain injury and to inflammatory and vasogenic proteins and the possible

modulating role of increased vagal activity in these patients.

Study description

Background summary

Severe traumatic brain injury is a devastating disease with 30% mortality and 40 % chronic disability. Outcome is determined by both the primary insult and secondary insults that thereafter. Prediction of outcome based on current methods (CT and MRI) is expensive, laborious, not consistently reliable and not universally available.

Study objective

Main objective is to find clinical, genetic, biochemical and immunological markers of primary and secondary traumatic brain injury with the highest precision in predicting outcome after severe traumatic brain injury. Secondary objective is to gain more insight in the pathophysiology of secondary brain injury and the development of brain oedema.

Study design

This is an interdisciplinary collaborative observational cohort study in patients with severe traumatic brain injury

Study burden and risks

The burden and risks associated with participation to this study are minimal. The total amount of blood samples is 640 ml in 10 days. Cerebrospinal fluid will only be collected if a drain is present and holds no risk for the patient. Most tests (including physical examination, Ct and MRI) are part of routine medical care of these critically ill patients. The MRI at 3 weeks and the neuropsychological testing is considered part of the protocol. This is a non-therapeutic study carried out in incapacitated patients. Since it involves patients after severe traumatic brain injury the subjects are incapacitated by definition.

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

Age >= 18
Severe TBI (GCS at first presentation <= 8)
Expected survival > 24 hours

Exclusion criteria

Pregnancy
No informed consent

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2007
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	NL18306.091.07