Functional and structural brain network parameters as prognostic factors in Traumatic Brain Injury (TBI)

Published: 03-03-2011
Last updated: 03-05-2024

The objectives of this study are to identify new prognostic factors for recovery after moderate/severe TBI and based on these factors to develop a grading scale for the post-traumatic disturbances of various cognitive and behavioural functions, in...

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

Summary

ID

NL-OMON34259

Source
ToetsingOnline

Brief title
Functional and structural brain network parameters in TBI

Condition

- Injuries NEC

Synonym
intracranial injury, traumatic brain injury

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universiteit Nijmegen
Source(s) of monetary or material Support: The Brain Foundation of the Netherlands (Hersenstichting Nederlands)

Intervention

Keyword: Connectivity, Network, Outcome, Traumatic brain injury

Outcome measures

Primary outcome

From the functional and structural connectivity networks the following network parameters will be assessed:

- Centrality of the removed nodes (regions). Centrality of a node measures how many of the shortest paths between all over node pairs in the network pass through it.

- Number of connections between the lesion site and the rest of the brain, that were lost.

- Local and nodal efficiency in the remaining network as the measure of its robustness.

The global clinical outcome of TBI patients will be evaluated using:

- extended Glasgow Outcome Scale (GOSE)

- functional independence measurement (FIM) score

- neurological examination.

A battery of neuropsychological tests will be performed to assess the outcome in:

- memory and executive function

- attention

- intellectual function

- speech/language.

Secondary outcome

The association between genetic polymorphisms and outcome.

Study description

Background summary

Traumatic brain injury (TBI) is a major cause of death and disability in many countries. The age range of peak TBI incidence is 15 to 24 years, therefore survivors may have relatively long life spans to cope with their impairments. Current imaging techniques for TBI diagnosis (CT and MRI) are able to identify structural lesions, however there is no direct correspondence between structural abnormalities and post-traumatic dysfunction or complaints. We suggest that poor outcome after moderate/severe TBI is associated with compromised brain network function rather than structural lesions per se. In this project we will examine the structural and functional connectivity between various brain regions in TBI patients. This connectivity will be further used to characterize the brain networks. By comparing the brain networks between TBI patients with good and poor outcome we will relate particular chronic symptoms to damage of particular brain network(s). Specifically the location and degree of damage of the affected networks will be considered as a potential prognostic factor for recovery of a particular brain function. In addition, possible mediating effects of genetic polymorphisms will be explored.

Study objective

The objectives of this study are to identify new prognostic factors for recovery after moderate/severe TBI and based on these factors to develop a grading scale for the post-traumatic disturbances of various cognitive and behavioural functions, in particular memory, executive function, and attention.

Study design

A cross-sectional observational study

Study burden and risks

The study only includes non-invasive procedures and risk for the subjects is minimal. We will ask the consent for one venapuncture. We expect two visits with a maximal total duration of 4 hours per participant.

Contacts

Public
Radboud Universiteit Nijmegen

Kapittelweg 29
6500 HB Nijmegen
NL
Scientific
Radboud Universiteit Nijmegen

Kapittelweg 29
6500 HB Nijmegen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Age >= 18 years and <= 65 years
- Gender: male and female
- Patients who were diagnosed a moderate or severe TBI > 1 year ago (only applicable to patients)
- Physical and cognitive abilities to undertake neuropsychological testing
- Willingness and ability to give written informed consent and willingness and ability to understand the nature and content, to participate and to comply with the study requirements

Exclusion criteria

- History of severe neurological or somatic disease

- Psychiatric diagnosis (current and past)
- Neurosurgical operations in past
- Chronic alcohol or drug abuse
- Everyday smoking
- Current use of any psychotropic drug
- Penetrating injury to the skull
- Pregnancy
- Metal objects in or around the body (braces, pacemaker, metal fragments, hearing devices)
- Claustrophobia

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-03-2011
Enrollment:	180
Type:	Actual

Ethics review

Approved WMO Date:	03-03-2011
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	NL34095.091.10