Multimodal brain monitoring in traumatic brain injury: A prospective observational cohort study

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Neurological disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON49495

Source
ToetsingOnline

Brief title
Multimodal brain monitoring in TBI

Condition

- Neurological disorders NEC

Synonym
acquired brain injury, Traumatic brain injury

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Intensive Care Centrum MST;geen externe financiering

Intervention

Keyword: CT perfusion, EEG monitoring, Transcranial doppler, Traumatic brain injury

Outcome measures

Primary outcome

Primary study parameters are:

- EEG measurements during the first seven days of ICU admission

- TCD measurements, performed twice a day during the first week

- ICP measurement (on indication)

- CT brain scan at admission

- CT brain perfusion scan at day 1 and day 7 (6-8)

The GOSE at 12 months (obtained by telephone), will be used as the primary outcome parameter.

Secondary outcome

Secundary study parameters are:

- Basic trauma and clinical data, including: age, sex, injury characteristics, initial GCS, GCS during ICU admission, pupillary abnormalities, pre-injury morbidity, haemodynamics, use of vasopressors (cumulative dose), saturation and glucose levels.

- CT and MRI data obtained for routine clinical practise

Secondary outcome parameters are:

- neurological outcome evaluated by the GOSE at hospital discharge and 6

months.

Study description

Background summary

Traumatic brain injury (TBI) is an important cause of death and disability especially in young adults. Treatment of this heterogeneous patient group is however challenging because of difficulties in monitoring real-time dynamics in brain dysfunction which may lead to secondary brain damage. Achieving an adequate cerebral bloodflow is of major importance in preventing such secondary cerebral damage which is the cornerstone of treatment in TBI. Cerebral perfusion computed tomography (CT perfusion) is a technique which makes it possible to rapidly and easily evaluate cerebral perfusion in different brain regions and therefore can identify brain areas which are prone to ischemia or hypoperfusion. Rapid fluctuations in cerebral hemodynamics are however not detected by imaging techniques such as computed tomography (CT) scans and magnetic resonance imaging (MRI). Therefore bedside tools for the assessment of cerebral perfusion are mandatory for on demand therapeutic interventions. Transcranial doppler (TCD) measures direct cerebral blood flow velocity, is non-invasive in nature, and can be performed semi-continuously. Electroencephalographic (EEG) monitoring also detects rapid changes in the function of regional cortical neurons and seems therefore promising in locating cortical regions vulnerable for secondary brain damage. Intracranial pressure (ICP) transducers give information about progressive intracerebral space occupying lesions leading to intracranial hypertension subsequently compromising cerebral blood flow.
Integrating the above mentioned tools and assessing their relations in terms of cerebral perfusion may lead to a specific model which gives a more detailed insight in the development and pathophysiological processes of secondary brain damage following the initial TBI.

Study objective

The primary objective is to study the relationship between these monitoring tools (TCD, EEG, ICP and CT perfusion) and the neurological outcome and to create a multimodal model for outcome prediction. The secondary objective is to study the functional relationships between the monitoring tools (TCD, continuous EEG, ICP measurement and CT perfusion).
Ultimately, we aim to develop an integrated model that leads to better recognition of pathophysiological changes after TBI and that can be used for the detection of secondary brain damage in an early stage.

Study design

This is a prospective, observational, single centre, cohort study.

Study burden and risks

There is no associated risk for participating patients. Continuous EEG and TCD are both non-invasive monitoring tools. The placement of an ICP transducer and serial native CT-imaging are part of normal clinical practice, so applying the study protocol does not introduce further risk to patients concerning these interventions. The introduction in the study protocol of a non-ionized iodinated contrast agent in cerebral perfusion computed tomography imaging of the brain introduces a very small risk for anaphylactic reactions, 1 to 2 per 10.000 interventions. In patients with normal renal function there is no associated risk for the development of contrast nephropathy. Patients with known renal dysfunction, who have a higher risk for contrast enhanced nephropathy, are excluded from the study protocol. Furthermore, the use of contrast agents in imaging in trauma patients is part of normal clinical practice. Follow-up will be performed by telephone at 6 and 12 months.

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

- Severe or moderate TBI (Glasgow Coma Scale of 3-12 measured at trauma site or the Emergency Department).
- Admission to the ICU.
- Age 18 years or older.

Exclusion criteria

- Patients after cardiopulmonary resuscitation with suspected postanoxic encephalopathy.
- Earlier hospitalization for TBI or stroke without full neurological recovery.
- Any progressive brain illness, such as a brain tumour or neurodegenerative disease.
- A limited life expectancy (<6 months).
- High risk for the development of iodine contrast induced nephropathy (according to local protocol).
- Women who are (potentially) childbearing.
- Contrast allergy.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-06-2017
Enrollment:	60

Type:	Actual

Ethics review

Approved WMO Date:	07-04-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	11-05-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	20-07-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	21-02-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL60512.044.17
Other	volgt