A new approach to determine the time of incidence of traumatic brain injury with chronic subdural hematomas.

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The aim of this study is to determine the time of incidence of TBI, by measuring the concentration of the biomarkers in CSDH and to investigate which method can be applied to determine the age of CSDH with hemoglobin derivatives.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON42525

Source
ToetsingOnline

Brief title
A new approach to determine the time of incidence of traumatic brain injury

Condition

- Other condition
- Central nervous system vascular disorders

Synonym
Chronic Subdural Hematomas - Traumatic Brain Injury

Health condition

traumatisch hersenletsel

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Biomarkers, Haemoglobin dervatives, post injury time, Traumatic brain injury

Outcome measures

Primary outcome

The concentration of 6 biomarkers (proteins) in the serum of the CSDH will be measured with an immunosorbent assay (ELISA) in order to determine the age of the CSDH.

Secondary outcome

Subsequently, the CSDH will be examined with reflection spectroscopy in order to measure the amount of hemoglobine derivatives in the CSDH.

Study description

Background summary

Studies have shown that age estimation of a CSDH with neuroimages (CT scans en MRI) is not reliable. A reliable method for the age estimation of the CSDH is necessary for the forensic field in order to determine the time of incidence of TBI. The current study will explore two methods for the age estimation of the CSDH: concentration determination of a group biomarkers* (proteins) and the determination of the hemoglobin derivatives. It is known that after TBI, certain cascades of recovery and breakdown occur in the brain, neural biomarkers (proteins) have an elevated concentration and hemoglobin derivatives will vary. Over the last decade the AMC forensic photonics group developed new methods for aging of hematomas (for child abuse recognition) and aging of blood ex vivo (for dating blood on the crime scene), both a first in the world. These studies used relative amounts of the various derivatives of hemoglobin to determine the age of the respective samples.The current study will study the hemoglobin derivatives in the CSDH samples in order to determine which aging model is appropriate for CSDH.

By measuring the concentration of the biomarkers in the CSDH (of different 'ages'), an age estimation can be done with a calibration curve (which is established in this study). As stated, the results are beneficial to the forensic field because determining the time of incidence of TBI via the age estimation of the CSDH can aid the reconstruction of activities and this in turn can be beneficial for the investigation. This information can then be used in court cases and for that reason these techniques are of high importance.
*Neuronal damage/growth (UCHL1, ICAM-5, NGF); Axonal damage (NFH); Astroglial cytoskeleton (GFAP); Myelin protein (MBP).

Study objective

The aim of this study is to determine the time of incidence of TBI, by measuring the concentration of the biomarkers in CSDH and to investigate which method can be applied to determine the age of CSDH with hemoglobin derivatives.

Study design

This is an observational study in which tests are performed on surgically removed CSDH that would otherwise be disposed. The method in which the CSDH is aquired differs minimal from the standard operation procedure, the risk for the patient is negligible.

Study burden and risks

The procedure to obtain the CSDH differs minimal from the standard operation procedure, and for that reason the risk for the patiënt will be negligible. Furthermore, explaining the study may be seen as a small burden by the patients.

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

* 18 years.
Mentally competent.
Informed consent.
CSDH as a consequence of traumatic brain injury (TBI).
Month of incidence of TBI is known.

Exclusion criteria

< 18 years.
Not mentally competent.
CSDH not as a consequence of TBI.
Unknown time of incidence of TBI.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-01-2016
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	03-09-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL53763.018.15