Prospective evaluation of the non-invasive ICP Headsense monitor in TBI patients undergoing invasive ICP monitoring

Published: 18-06-2014
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To compare the accuracy of HeadSense*s non-invasive ICP monitor with the readings from the invasive ICP monitor.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Increased intracranial pressure and hydrocephalus
Study type	Observational non invasive

Summary

ID

NL-OMON41180

Source
ToetsingOnline

Brief title
Evaluation of non-invasive ICP Headsense monitor

Condition

- Increased intracranial pressure and hydrocephalus

Synonym
neurotrauma

Research involving
Human

Sponsors and support

Primary sponsor: Sint Elisabeth Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Headsense, Intracranial pressure, Neurotrauma, TBI

Outcome measures

Primary outcome

Demonstrate the HS-1000 performance and accuracy in ICP monitoring

Secondary outcome

ergonomics and functionality

Study description

Background summary

Patients with severe traumatic brain injury (TBI) are admitted to the ICU. Under certain condition (such as a impaired consciousness) the intracranial pressure is measured. An increase in the intracranial pressure might suggest secondary neurological deterioration and is considered an alarming symptom. Current practice is to insert an invasive monitor through a burr hole in the skull with the risk of bleeding and infection. Using a new type of ICP monitor (Headsense) it is possible to measure ICP non-invasively through an acoustic signal

Study objective

To compare the accuracy of HeadSense*s non-invasive ICP monitor with the readings from the invasive ICP monitor.

Study design

A comparison of ICP values from both invasive ICP monitor, and HeadSense*s non-invasive ICP monitor.

Study burden and risks

This project is a pilot study. Family of patients will be asked for consent.
The measurement is non-invasive without any known negative side effects for the patients. The measurements will not interfere with current best practice.
Readings from the headsense will not be used for clinical decisions. The

patient will not benefit from the extra measurements

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 traumatic brain injury, age18-85 years, ICU admitted, invasive ICP monitor

Exclusion criteria

ear infection, pregnancy

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2014
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	18-06-2014
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL48862.028.14