Changes in middle cerebral artery pulsatility in severe head injury patients with ICP-monitoring: relation with autoregulation.

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To gain understanding about the changes in intracranial hemodynamics in severe head injury. To improve the early detection of an autoregulation syndrome.

Ethical review	Approved WMO
Status	Pending
Health condition type	Central nervous system vascular disorders
Study type	Observational non invasive

Summary

ID

NL-OMON31188

Source
ToetsingOnline

Brief title
Artery pulsatility in severe head injury patients with ICP monitoring.

Condition

- Central nervous system vascular disorders

Synonym
cerebral blood flow, concussion

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: mede gefinancierd vanuit IAG subsidie

(vanuit de Europese Unie),Neuromon BV

Intervention

Keyword: autoregulation, brain injury, hemodynamics

Outcome measures

Primary outcome

Measurement of PaR value for the right and left middle cerebral artery on day

0-5 after admission in relation to the mean arterial blood pressure and the

end-tidal carbon dioxide.

Secondary outcome

not applicable

Study description

Background summary

In the first few days after traumatic brain injury an increased risk for the development of secondary changes due to cerebral oedema and haemorrhage is present. To provide an optimal cerebral perfusion, the regulation of the blood pressure is one of the main goals during the first days after admission. All patients are admitted to the ICU and an intracranial pressure (ICP) device is inserted to measure the intracranial pressure. With the ICP in combination with the blood pressure (ABP) the cerebral perfusion pressure is calculated. Treatment of the patient is guided by changes in ICP and CPP. The property of the cerebral arteries to adjust to changes in blood pressure to provide an optimal cerebral blood flow is called the cerebral autoregulation. Some patients with ICP-monitoring develop disturbed autoregulation with subsequent increase of ICP with oedema and risk of cerebral herniation.
In the present investigation the management protocol is expanded by a simultaneous recording of bilateral TCD signals combined with the end-tidal carbon dioxide and the arterial blood pressure. All additional signals are recorded non-invasively. The recording of these extra signals will allow the calculation of a so-called PaR-value, which hypothetically provides better information on intracranial hemodynamics than ICP alone
Firstly, this study is a feasability study (can all non-invasive data be acquired succesfully?), secondly it is a pilot observational study (can values

for the PaR parameter be related to changes in the patients clinical condition?).

Study objective

To gain understanding about the changes in intracranial hemodynamics in severe head injury. To improve the early detection of an autoregulation syndrome.

Study design

Instead of the usual monitoring of cerebral perfusion pressure with ICP-monitoring, the study is designed to record simultaneously with the ICP bilateral TCD signals combined with the end-tidal carbon dioxide and the arterial blood pressure. All signals are recorded non-invasively. Combining the TCD signal with the ABP signal will allow the calculation of the so-called pulsatile apparent resistance or PaR, a parameter that has been shown to provide better information on intracranial hemodynamics than ICP and or TCD alone.

Study burden and risks

The subjects will undergo daily PaR-measurement during the first 5 days after admission. The usual TCD examination takes about 30 minutes, whereas the PaR measurement takes roughly 60 minutes (30 min. preparation; 30 min. actual measurement).
As the PaR-measurements all are non-invasive and are done in patients who are sedated for ICP-monitoring no significant burden or risk for the patient is present.

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

Glasgow Coma Scale <=8
- age > 17 years

Exclusion criteria

age < 18 years; carotid occlusion or severe stenosis in history

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2007
Enrollment:	20

Type:	Anticipated

Ethics review

Approved WMO Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL17614.042.07