Continuous neuromonitoring in critically ill patients.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27058

Source
NTR

Health condition

Intensive care, EEG, neuromonitoring, coma

Sponsors and support

Primary sponsor: Maastricht University Medical Centre
Source(s) of monetary or material Support: Maastricht University Medical Centre

Intervention

Outcome measures

Primary outcome

The main study endpoint is the sensitivity and specificity of the developed monitoring tool for detection of secondary events (seizures, focal cerebral ischemia) as compared to the gold standard (evaluation of the EEG by a clinical neurophysiologist).

Secondary outcome

Secondary objectives are mainly observation of clinical data and events which are useful for the future implementation of the developed monitoring device. Topics to be described and

questions to be answered are (amongst others):

1. The prevalence of nonconvulsive seizures in critically ill patients;

2. What patients groups are most at risk for developing seizures?;

3. Does the information gained by cEEG measurement have impact on clinical patient management, for instance on therapeutic decision making?;

4. Is it possible to detect the development of cerebral ischemia by continuous EEG monitoring before clinical symptoms occur?;

5. Is brain function, as measured by cEEG monitoring, influenced by general health events such as hypotension, bradycardia and decrease of oxygen saturation?

Study description

Background summary

Several neurological disorders are not clinically detectable in critically ill patients. Continuous monitoring of brain function can reveal some of these disorders. Discovery of these events could potentially lead to therapeutic interventions to prevent further damage to the brain and thereby improve outcome. Neither continuous neuromonitoring of this population, nor therapeutic interventions on this basis are however part of contemporary routine practice.

Objective: The primary objective of this study is to develop and implement the use of an EEG-tool to monitor brain function in all adult patients at risk for deterioration of brain function, development of (non)convulsive seizures or cerebral ischemia. The tool should be reliable, easy to use by ICU personnel and allow remote monitoring by the clinical neurophysiologist.

Study objective

The main study endpoint will be the sensitivity and specificity of the developed monitoring system for detection of secondary events (seizures, focal cerebral ischemia) as compared to the gold standard (evaluation of the EEG by a clinical neurophysiologist).

Study design

N/A

Intervention

N/A

Contacts

Public
V.H.J.M. Kranen-Mastenbroek, van
[default]
The Netherlands
+31 (0)43 3877272
Scientific
V.H.J.M. Kranen-Mastenbroek, van
[default]
The Netherlands
+31 (0)43 3877272

Eligibility criteria

Inclusion criteria

1. Age 18 years or older;

2. Glasgow coma scale < 9;

3. Admitted to the ICU;

4. One of the following conditions: Intracerebral hemorrhage; subarachnoid hemorrhage; ischemic stroke; severe traumatic brain injury; (meningo)encephalitis; post-anoxic encephalopathy; intracranial surgery; (non)convulsive status epilepticus; cardiac arrest or ventricular fibrillation with cardial resuscitation.

Exclusion criteria

Severe skull injuries making EEG-electrode application impossible.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2010
Enrollment:	150
Type:	Anticipated

Ethics review

Positive opinion

Date:	25-05-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 34917
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2207

Register	ID
NTR-old	NTR2331
CCMO	NL30161.068.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON34917

Study results

Summary results
N/A