Postanoxic encephalopathy: The prognostic value of EEG, TMS and SSEP

Published: 31-05-2010
Last updated: 03-05-2024

To evaluate the prognostic value of the EEG, including quantitative EEG features, TMS and SSEP after out-of-hospital cardiac arrest.

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

Summary

ID

NL-OMON34329

Source
ToetsingOnline

Brief title
Prognosis in postanoxic encephalopathy

Condition

- Encephalopathies

Synonym
postanxic encephalopathy; cerebral ischaemia; lack of oxygenation in the brain due to a cardiac arrest

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Twente
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Electroencephalography (EEG), Postanoxic encephalopathy, Somatosenosry evoked potential (SSEP), Transcranial magnetic stimulation (TMS)

Outcome measures

Primary outcome

The main study parameters are the EEG trend curves obtaind by extracting quantitative EEG features from the raw EEG data, as well as the TMS and SSEP responses measured during the first days after hospital admission. These parameters will be compared with the neurological outcome of the patient measured on the Glasgow-Pittsburgh Cerebral Performance Categroy (CPC) score and EQ-6D questionnaire.

Secondary outcome

The EEG, TMS and SSEP parameters measured after 1 and 3 months.

Study description

Background summary

Survival rate after cardiac arrest is poor. Neurologic recovery is determined primarily by the extent of postanoxic encephalopathy (PAE). An early neurologic prognosis could be very helpful in these PAE patients. Absence of short latency somatosensory evoked potential (SSEP) has a good predictive value for poor prognosis in these patients. However, its sensitivity is only moderate. Also the electroencephalogram (EEG) has shown to correlate with the neurological outcome of PAE patients. Nevertheless, it is still impossible to give an early reliable prognosis for an individual patient. We hypothesize that the prognosis in PAE patients could be improved with continuous EEG monitoring and the addition of quantitative EEG features that can be extracted from the raw EEG data. Hereby not only the absolute value of the quantitative EEG features could be useful, but the trend of these features over the first days might be even more interesting. Furthermore, by combining these EEG parameters with short latency, as well as long latency SSEP measurements and the evaluation of the transcranial magnetic stimulation (TMS) response, additional improvement in

prognosis may be feasible. To test this hypothesis we want to give PAE patients admitted to the ICU for hypothermia treatment TMS stimuli once a day and do a follow-up study in 20 of these PAE patients with a good neurological outcome.

Study objective

To evaluate the prognostic value of the EEG, including quantitative EEG features, TMS and SSEP after out-of-hospital cardiac arrest.

Study design

Prospective observational study

Study burden and risks

We will perform a TMS measurement once a day during the first days (day 2 - day 5) of admission to the ICU. Patients with a good neurological outcome will be asked to participate in the follow up study. In this follow-up study the patients have to visit the hospital twice (1 and 3 months after their admission to the ICU) for an EEG, TMS and SSEP measurement. All measurements are non-invasive, will only produce minor discomfort to the patient and do not have associated risks.

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

- Cardiac arrest
- Admitted to the ICU for therapeutic hypothermia
- Age above 18 years
- Obtained informed consent

Exclusion criteria

- Terminal illness
- Psychoactive or anticonvulsive medication
- Known history of a neurologic disease (stroke, parkinson, epilepsy)
- Known history of brain surgery or severe brain trauma
- Known history of drug or alcohol abuse
- Severe neuropathy in the arms
- Not having two arms

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-06-2010
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	31-05-2010
Application type:	First submission
Review commission:	METC Twente (Enschede)

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	NL32007.044.10