Prognosis in postanoxic encephalopathy.

No registrations found.

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

Summary

ID

NL-OMON26463

Source
Nationaal Trial Register

Brief title
Prognosis in postanoxic encephalopathy

Health condition

In English
Postanoxic encephalopathy
Electroencephalography (EEG)
Transcranial magnetic stimulation (TMS)
Somatosenosry evoked potential (SSEP)

In Dutch:
Postanoxische encefalopatie
Elektroencefalografie (EEG)
Transcraniële magnetische stimulatie (TMS)
Somatosenosry evoked potential (SSEP)

Sponsors and support

Primary sponsor: MJAM van Putten MD PhD (Neurologist)
Medisch Spectrum Twente
Afdeling Klinische Neurofysiologie
Source(s) of monetary or material Support: University of Twente

Intervention

Outcome measures

Primary outcome

The main study endpoints will be the neurological outcome of the patient measured on the Glasgow-Pittsburgh Cerebral Performance Category (CPC) and EEG, TMS and SSEP measurements after one and three months. The endpoint will be compared with the quantitative EEG features that can be extracted from the raw EEG data and the TMS and SSEP responses measured at the ICU in the first days after the cardiac arrest.

Secondary outcome

The CPC determined six months after cardiac arrest by telephone.

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 PAE patient. We hypothesize that this prognosis could be improved by combining SSEP measurements with continuous EEG monitoring and transcranial magnetic stimulation (TMS) measurements. With the addition of quantitative EEG features that can be extracted from the raw EEG and the use of continuous EEG recordings, providing trend curves, we hypothesize that prognostication can be significantly improved. To test this hypothesis, we aim to do a follow-up study in PAE patients, which were previously admitted to our ICU for hypothermia treatment. These patients are monitored by continuous EEG and SSEP measurements during their first days of admission at the ICU. During this period we want to measure the response of a TMS pulse once a day as well. We will correlate these data with the Glasgow-Pittsburgh Cerebral Performance Category (CPC). To examine the recovery in patients with good neurological outcome in more detail, we want to do a follow-up study with additional EEG, TMS and SSEP measurements after one and three months in 20 PAE patients with good neurological outcome (CPC≤3).

Study objective

We hypothesize that the neurologic prognosis of patients with post-anoxic encephaloptahy

(due to a cardiac arrest) could be improved by combining SSEP measurements with continuous EEG monitoring and transcranial magnetic stimulation (TMS) measurements. With the addition of quantitative EEG features that can be extracted from the raw EEG and the use of continuous EEG recordings, providing trend curves, we hypothesize that prognostication can be significantly improved.

Study design

1. EEG, TMS and SSEP Measurements during the first 5 days of hopital admission;

2. Follow up EEG, TMS and SSEP measurements after 1 and 3 months;

3. CPC score after 6 months.

Intervention

None.

Contacts

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Eligibility criteria

Inclusion criteria

1. Cardiac arrest;

2. Admitted to the ICU for therapeutic hypothermia;

3. Monitored with continuous EEG during the first 5 days of their hospital admission, or until the patient was extubated or discharged from the ICU;

4. Age above 18 years;

5. Obtained informed consent.

Exclusion criteria

1. Terminal illness;

2. Psychoactive or anticonvulsive medication;

3. Known history of a neurologic disease (stroke, parkinson, epilepsy);

4. Known history of brain surgery or severe brain trauma;

5. Known history of drug or alcohol abuse;

6. Severe neuropathy in the arms;

7. Not having two arms.

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:	Recruiting
Start date (anticipated):	15-04-2010
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	17-03-2010
Application type:	First submission

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
NTR-new	NL701
NTR-old	NTR2244
Other	METC Medisch Spectrum Twente : P10-017
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A