Prognosis in postanoxic encephalopathy.

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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)...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26463

Bron
Nationaal Trial Register

Verkorte titel
Prognosis in postanoxic encephalopathy

Aandoening

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)

Ondersteuning

Primaire sponsor: MJAM van Putten MD PhD (Neurologist)
Medisch Spectrum Twente
Afdeling Klinische Neurofysiologie
Overige ondersteuning: University of Twente

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

None.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	15-04-2010
Aantal proefpersonen:	20

Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	17-03-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL701
NTR-old	NTR2244
Ander register	METC Medisch Spectrum Twente : P10-017
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A