BROCA-prediction: Brain outcome after cardiac arrest prediction

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Long-term cognitive, emotional and functional disturbances after cardiac arrest can be predicted based on early demographic, clinical, EEG, and MRI measures.

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

Samenvatting

ID

NL-OMON27782

Bron
NTR

Verkorte titel
BROCA-prediction

Aandoening

Cardiac arrest, postanoxic encephalopathy

Ondersteuning

Primaire sponsor: University of Twente, Clinical neurophysiology, Drienerlolaan 5 7522NB Enschede
Overige ondersteuning: Nederlandse Hartstichting

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome measure (i.e. predicted outcome) is ‘restrictions in participation’ according to the restrictions subscale of the USER-P, dichotomized as ‘2 or more restrictions’

vs. ‘0 or 1 restriction’ at 12 months.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: In survivors after cardiac arrest, the reported incidence of cognitive and emotional disturbances is high. These may lead to functional impairments and restrictions in participation. Early prediction of cognitive disturbances, levels of activity, or restrictions in participation would support rehabilitation, but are unavailable.

Objective: Primary objective is to create a prediction model based on clinical factors derived from early screening of motor, cognitive, and emotional functioning to predict restrictions in participation at one year after cardiac arrest. Secondary objectives include prediction models for cognitive disturbances and levels of activity, and to study additional predictive values of EEG and MRI measurements.

Study design: This will be a prospective, longitudinal, multicenter cohort study. Patients will be included, and clinical, MRI, and EEG measures of brain damage will be collected 4 +/- 3 weeks after cardiac arrest, during admission on cardiac care units or cardiology departments. Follow-up will be one year.

Study population: 200 adult patients after cardiac arrest and cardiopulmonary resuscitation, that have survived the acute phase and awakened from coma.

Main study parameters/endpoints: The primary outcome measure (i.e. predicted outcome) is ‘restrictions in participation’ according to the restrictions subscale of the USER-P, dichotomized as ‘2 or more restrictions’ vs. ‘0 or 1 restriction’ at 12 months. Secondary outcome measures (i.e. predicted outcomes) include cognitive disturbances, levels of activity, and sleep disturbances at 12 months. Determinants (i.e. independent variables) will be collected at 4 +/- 3 weeks after cardiac arrest and include demographic factors, clinical factors, MRI, and EEG measurements.

Doel van het onderzoek

Long-term cognitive, emotional and functional disturbances after cardiac arrest can be predicted based on early demographic, clinical, EEG, and MRI measures.

Onderzoeksopzet

Hospital screening (including MRI and EEG): 4 +/- 3 weeks after CA
Follow-up (questionnaires): 3, 6 months
Neuropsychological examination, polysomnography, questionnaires: 12 months

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age ≥ 18 years
- Out of hospital cardiac arrest
- Successful cardiopulmonary resuscitation 4 +/- 3 weeks ago
- GCS score > 8
- Admission to cardiac care or cardiology department
- Written informed consent obtained

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Primary cause of arrest is choking or hanging
- Cardiac arrest and resuscitation started in the ambulance, on the way to the hospital, with return of spontaneous circulation and consciousness upon arrival at the hospital
- Preexistent brain damage with mRS>2
- Known progressive neurodegenerative disease
- Life expectancy of less than three months as a result of another medical condition
- Need of intravenous sedative medication
- Insufficient knowledge of the Dutch language to fill out questionnaires
- Patients with an MRI incompatible Implantable Cardioverter Defibrillator (ICD) may be

excluded from the MRI protocol, depending on the ICD type. These patients can be included in the remainder of the study.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-11-2019
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	02-05-2021
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	NL9451
Ander register	CCMO Arnhem-Nijmegen : 2019-5399

Resultaten