BROCA-prediction: Brain outcome after cardiac arrest prediction

No registrations found.

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

Summary

ID

NL-OMON27782

Source
Nationaal Trial Register

Brief title
BROCA-prediction

Health condition

Cardiac arrest, postanoxic encephalopathy

Sponsors and support

Primary sponsor: University of Twente, Clinical neurophysiology, Drienerlolaan 5 7522NB Enschede
Source(s) of monetary or material Support: Nederlandse Hartstichting

Intervention

Outcome measures

Primary outcome

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

Secondary outcome measures (i.e. predicted outcomes) at 12 months include:
- Cognitive disturbances as measured by detailed NPE consisting of MoCA, 15 word test, RAVEN, Trail Making Test (TMT), Stroop, star cancellation, Boston Naming Test (BNT), and letter fluency
- Levels of activity as measured by USER-P and EQ5D-5L
- Emotional disturbances as measured by the Hospital Anxiety and Depression Scale (HADS)
- Sleep as assessed by the Pittsburgh Sleep Quality Index (PSQI) and polysomnography
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.

Study description

Background summary

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.

Study objective

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

Study design

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

Contacts

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Eligibility criteria

Inclusion criteria

- 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

Exclusion criteria

- 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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2019
Enrollment:	200
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	02-05-2021
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	NL9451
Other	CCMO Arnhem-Nijmegen : 2019-5399

Study results