The course of cognitive functioning in the first year after an out of hospital cardiac arrest (OHCA)

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

Summary

ID

NL-OMON48532

Source
ToetsingOnline

Brief title
Cognitive recovery in the first year after a cardiac arrest.

Condition

- Cardiac arrhythmias
- Neurological disorders NEC
- Disturbances in thinking and perception

Synonym
cognition, memory

Research involving
Human

Sponsors and support

Primary sponsor: Viecuri Medisch Centrum voor Noord-Limburg

Source(s) of monetary or material Support: Wetenschapsfonds Viecuri Medisch Centrum

Intervention

Keyword: cardiac arrest, cognitive functioning, outcome, resuscitation

Outcome measures

Primary outcome

The main study parameters are the cognitive impairments i.e. the neuropsychological parameters for impairments in perception, language, memory, attention, reasoning and executive functioning 2, 6 and 12 months after an OHCA.

Secondary outcome

The secondary parameters are the delay time to BLS, length of ICU-stay, duration of mechanical ventilation, severity of delirium and lowest registered blood pressure and arterial saturation. Demographic parameters (age, gender, level of education), the affective state and PTSD are covariates.

Study description

Background summary

An out of hospital cardiac arrest (OHCA) is common (30-40 pers/100.000/y in the Netherlands alone) and has a total mortality risk of 75%. Patients who have been successfully resuscitated after a cardiac arrest are at risk to experience long-term cognitive, emotional and/or physical impairments. E.g., between 30 and 50 % of survivors experience cognitive deficits for up to several years post-discharge. The majority of studies investigate the cognitive functioning and the long-term impairment, but it is less known to what degree cognitive functioning may recover over time. In this study we will measure cognitive recovery of OHCA survivors and explore if there are causalities related to parameters of the ICU stay

Study objective

The general aim of this study is to investigate the course of cognitive functioning during the first year after an OHCA. In order to find correlations which might suggest treatable causalities, cognitive functioning will be linked to parameters routinely collected shortly before and during the ICU stay, such as delay time to BLS, length of ICU-stay, duration of mechanical ventilation, severity of delirium and lowest registered blood pressure and arterial saturation. We expect that the parameters routinely collected shortly before and during ICU stay will be correlated negatively to (the course of) cognitive functioning in the first year after an OHCA.

Study design

This is a one-year follow-up prospective cohort-study.
The participants will be assessed with:
1. Neuropsychological tests
2. Questionnaires in Castor (online questionnaire)
The neuropsychological tests and the questionnaires in Castor will be administered three times during the first year after an OHCA; 2-3 months (T1), 6 months (T2) and 12 months (T3). The moment of neuropsychological assessment will have a range of -7/+7 days. The Questionnaires have to be filled in from one weeks before the neuropsychological testing to ultimately at the same day in addition to the assessment (see figure 3.1 timeline).

For each participant in this study clinical and demographic characteristics will be prospectively collected in a database:
- Demographic: Age, gender, level of education.
- Parameters routinely collected shortly before and during the ICU stay; like length delay to BLS, length of ICU stay, length of mechanical ventilation, severity of delirium and lowest registered blood pressure and arterial saturation.
- Medical history.
- Type and dose of medication.

Duration:
The study will collect participants for 2,5 years after the first participant is included. All participants will be followed for 1 year. The maximum duration of the study will be 3,5 years (2,5 years of including, 1 year follow-up).

Study burden and risks

Patients who are included in the study will be asked to visit the hospital 3 times for a 60-75 minutes neuropsychological testing and 30 minutes of questionnaires. In some cases this might be physically or psychologically strenuous. Reliving memories might distress some participants. However, according to experience based practice, the possibility to talk about their clinical period is often experienced as releasing.

The outcomes of neuropsychological assessment can be stressing especially when cognitive impairments are found. However, once serious problems are found, this will give the opportunity to refer to specialists who can treat these problems who would otherwise gone unnoticed or treated or dealt with in a less adequate or even worsening way.
A small financial compensation for travelling costs is provided for.

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

Patients of 18-85 years.
Resuscitated out of hospital.
Discharged from the hospital within 2 months after resuscitation.
First cardiac arrest.

Ability to visit the hospital at 2-6 and 12 months.

Exclusion criteria

In hospital resuscitation.
Futile care in case mortality is expected within 12 months.
Unable to communicate, read or understand information read aloud for them.
Acquired brain injury, neurodegenerative disease or brain surgery in the medical history.
Native language other than Dutch.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2020
Enrollment:	58
Type:	Actual

Ethics review

Approved WMO

Date:	31-10-2019
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL71281.015.19