# Cracking Coma: towards EEG and MRI based precision medicine after cardiac arrest

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1. To estimate the additional value of early MRI monitoring for the prediction of neurological outcome of comatose patients after cardiac arrest. 2. To gain insight in the pathophysiology of PAE by functional MRI measures and by associating MRI...

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Heart failures |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON52980

**Source**
ToetsingOnline

**Brief title**
Cracking Coma

### Condition

- Heart failures
- Encephalopathies

**Synonym**
coma due to cardiac arrest, hypoxic coma

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Rijnstate Ziekenhuis
**Source(s) of monetary or material Support:** Rijnstate Radboud promotiefonds

## Intervention

**Keyword:** EEG, MRI, Post Anoxic Coma, Prognosis

## Outcome measures

### Primary outcome

The primary outcome measure is neurological outcome, defined as the score on the Cerebral Performance Category (CPC) at six months, dichotomized as good (CPC 1-2 = no or moderate neurological disability) or poor (CPC 3-5 = severe disability, coma, or death)

### Secondary outcome

Secondary outcome measures include cognitive functioning, depression, and quality of life at one year, as well as histopathological damage of brain tissue of non-survivors.

# Study description

### Background summary

30-70% of comatose patients admitted to the intensive care unit (ICU) after cardiac arrest never regain consciousness as a result of post anoxic encephalopathy (PAE). Early identification of patients without potential for recovery of brain functioning may prevent inappropriate continuation of medical treatment and improve communication between doctors and patients. However, current diagnostic and prognostic measures can identify only 20-50% of the patients with irreversible brain damage, precluding cerebral recovery and awakening. Also, the pathophysiology of brain damage is largely unclear. New magnetic resonance imaging (MRI) sequences hold potential to substantially improve outcome prediction.

### Study objective

1. To estimate the additional value of early MRI monitoring for the prediction of neurological outcome of comatose patients after cardiac arrest.
2. To gain insight in the pathophysiology of PAE by functional MRI measures and

by associating MRI findings with histopathological studies of brain tissue obtained from non-survivors.

### Study design

Prospective cohort study

Intervention: In addition to standard treatments, patients will undergo MRI scanning of the brain at day 3, 7, and three months after cardiac arrest. A subgroup of patients will be scanned within 24 hours after cardiac arrest, to assess feasibility and to gain more insight in the evolution of brain damage in PAE. Survivors will be followed for one year. Outcome measurements will focus on disabilities, quality of life, and depression.

### Study burden and risks

MRI is a daily used imaging technique with no known short term or long term harm. Transport of comatose patients from the ICU to the radiology department introduces a risk in case of hemodynamic or pulmonary instability. To minimize this risk, only patients that are considered stable will be transported to undergo MRI. A physician and ICU nurse will accompany the patient at all times during transport and scanning. All materials necessary for continuous monitoring and treatment, together with materials for emergency situations, are stored in a mobile trolley. The medical team can act immediately in case of complications. The MR signal will not interfere with patient treatment and will cause no damage to the patients. Participation in this trial will not change, delay, or interfere with standard treatment, nor will it change the ICU or hospital admission time. Herewith, risk of participation is considered negligible

## Contacts

**Public**
Rijnstate Ziekenhuis

Wagnerlaan 55
Arnhem 6815AD
NL
**Scientific**
Rijnstate Ziekenhuis

Wagnerlaan 55
Arnhem 6815AD
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

Comatose, defined as Glasgow Coma Score <= 8
Age >= 18 years
Cardiac arrest with a presumed cardiac cause of the arrest or caused by lungembolism
Admission on ICU

## Exclusion criteria

Pregnancy
Life expectancy < 24 hours
Absence of written informed consent (by a legal representative)
Any known progressive brain illness, such as a brain tumor or neurodegenerative disease.
Known contra-indication for MRI
Preexistente afhankelijkheid (CPC3-4)

# Study design

## Design

**Study type:** Observational non invasive

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| Masking: | Open (masking not used) |
| Control: | Uncontrolled |

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| Primary purpose: | Basic science |

### Recruitment

NL

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| Recruitment status: | Recruiting |
| Start date (anticipated): | 12-06-2018 |
| Enrollment: | 100 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 09-05-2018 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 18-02-2019 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 12-12-2019 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 16-11-2022 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |

## 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 |
|---|---|
| ClinicalTrials.gov | NCT03308305 |
| CCMO | NL62151.091.17 |