

# Cognitive impairment following cardiac arrest and Target Temperature Management

## (A sub-study of the TTM Trial)

Published: 12-12-2012

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Understanding the cognitive disorders in patients who have woken up after a resuscitation and who were treated with a controlled temperature during the ICU treatment

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Mental impairment disorders
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON36855

### Source

ToetsingOnline

### Brief title

Cognitive impairment following cardiac arrest

### Condition

- Mental impairment disorders

### Synonym

cognitive disorders, memory and concentration disturbances

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** Hartstichting Zweden

## Intervention

**Keyword:** Cardiac arrest, Cognitive impairment, Temperature Management

## Outcome measures

### Primary outcome

Comparing scores on cognitive test scales between patients after cardiac arrest treated with 33 or 36 degrees and patients after myocardial infarction.

### Secondary outcome

Comparing the intensity of care for the carers between patients after cardiac arrest and patients after myocardial infarction

## Study description

### Background summary

During cardiac arrest, brain damage occurs. This condition is called a postanoxic encephalopathy. Clinically, this is reflected in a persistent coma, but the patient may also wake up and recover well. In recent years it has become clear that patients who made a "good" recovery suffer from cognitive disorders. Which disturbance this and how they interfere with the daily functioning of the patients is unknown.

### Study objective

Understanding the cognitive disorders in patients who have woken up after a resuscitation and who were treated with a controlled temperature during the ICU treatment

### Study design

international multicenter prospective study

### Study burden and risks

There is no risk in this study. The entire cognitive test will take 2 hours which can be a burden for the patient. This will be explained to the patient

who can at any time indicate that he / she wants to stop.

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

1. TTM study patients who are alive at six-month follow-up and give consent to the cognitive sub-study
2. Informants (usually a relative or close friend/caregiver) of the patient above (1) who give consent to the cognitive sub-study
3. STEMI patients at the given centre, the sex-matched patient who best fits in age to the TMM patient above (1) with a similar date of infarct who gives consent to the cognitive sub-study
4. Informants (usually a relative or close friend/caregiver) of 3 above who give consent to participate.

## Exclusion criteria

The same exclusion criteria as for the main TTM study with the addition that control patients should not have a history of cardiac arrest.

Exclusion criteria TTM study: Conscious patients, pregnancy, out-of-hospital cardiac arrest of presumed non-cardiac cause, cardiac arrest after arrival in hospital, known bleeding diathesis, suspected or confirmed acute intracranial bleeding, suspected or confirmed acute stroke, temperature on admission <30°C, unwitnessed asystole, persistent cardiogenic shock, known limitations in therapy, known disease making 180 day survival unlikely, known pre-arrest cerebral performance category 3 or 4, >240 minutes from ROSC to randomisation, no informed consent.

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

**Primary purpose:** Treatment

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	12-03-2013
Enrollment:	85
Type:	Actual

## Ethics review

Approved WMO	
Date:	12-12-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	

Date: 12-02-2013  
Application type: Amendment  
Review commission: METC Amsterdam UMC

## 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	NL40826.018.12