Cognitive impairment following cardiac arrest and Target Temperature Management (A sub-study of the TTM Trial)

Published: 12-12-2012
Last updated: 26-04-2024

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

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mental impairment disorders
Study type	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
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

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