Coronary angiography after cardiac arrest

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON50572

Source
ToetsingOnline

Brief title
the COACT trial

Condition

- Coronary artery disorders

Synonym
cardiac arrest

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Astrazeneca

Intervention

Keyword: cardiac arrest, coronary angiography

Outcome measures

Primary outcome

The primary end point of the study is 90-days survival

Secondary outcome

Secondary endpoints are 90-days survival with good, minor or moderate disability, myocardial injury measured by troponine and CK MB as area under the curve, occurrence off acute kidney injury, need for renal replacement therapy, time to target hypothermia, neurological status at ICU discharge and duration of inotropic support, left ventricular function on cardiac ultrasound or MRI (if available), functional performance measured with the RAND 36 questionnaire at 1 year and MACE and survival at 1 and 5 years.

Study description

Background summary

Cardiac arrest is one of the leading causes of death in the western world. Patients after a succesfull resuscitation are frequently presented to the ER. Although the resuscitation was succesfull and circulation was restored, most patients are unconscious and mechanically ventilated. The prognoses of these patients remains poor due to damage to brain and heart. If the EKG shows signs of a lage myocardial infarction (STEMI), there is a indication for acute coronary angiography and primairy PCI. This is based on several randomised trials in patients with STEMI (although patients after cardiac arrest were often not included in these trials). In resuscitated patients without signs of STEMI the quistion also rises wether an acute coronary angiography will benefit the patient before being admitted to the ICU. This is based on several observational studies who have shown a survival benefit in patients after acute coronary angiography. These studies are however not radomised and subject to selection bias. Futhermore several radomised trials showed an acute coronary

angiography not to be superior to delayed coronary angiography in patients with non ST segment elevation myocardial infarction (NSTEMI) who were not resuscitated. To answer this important clinical question a randomised trial is necessary.

Study objective

Aim of the COACT trial is to compare a strategy of immediate coronary angiography followed by percutaneous coronary intervention (PCI) if indicated with delayed coronary angiography in patients presenting at the emergency department after out of hospital cardiac arrest without signs of a ST segment elevation myocardial infarction (STEMI) and no obvious non-cardiac aetiology. This will be the first randomised trial adressing this subject and will have the potential to influence international guidelines.

Study design

study is a prospective, randomized controlled, multi-centre study

Intervention

The patients will be randomized to either the immediate or delayed coronary angiography and subsequent revascularisation group

Study burden and risks

The risk and burden consists of early or late CAG. If PCI is indicated, early CAG will turn into a benefit by preventing further myocardial ischemia. If no indication for PCI is found, the CAG will be futile. This may be the case in both groups . During early CAG, the patient is under anaesthesia and will not be aware of the intervention. Potential medical risks of futile CAG include access site bleeding and contrast induced nephropathy One of the treatment groups may have better outcome.

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

Age > 18
Comatose patients (Glasgow coma score < 8) with ROSC after OHCA
Ventricular tachycardia or ventricular fibrillation as initial arrest rhythm
Without signs of STEMI.

Exclusion criteria

Signs of STEMI on the ECG at the emergency department (including new LBTB or isolated ST depression in V1-V3 due to an true posterior infarct).
Hemodynamic instability unresponsive to medical therapy (defined as a systolic blood pressure < 90 mm Hg).
An obvious or suspected non cardiac aetiology of the cardiac arrest.
A known severe renal dysfunction. (GRF< 30 ml/min)
Obvious or suspected pregnancy
Suspected or confirmed acute intracranial bleeding
Suspected or confirmed acute stroke
Known limitations in therapy or DO Not Resuscitate-order.
Known pre-arrest Cerebral Performance Category 3 or 4
>4 hours (240 min from ROSC to screening
Known inability to complete 90 day follow up

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-01-2015
Enrollment:	552
Type:	Actual

Ethics review

Approved WMO Date:	12-11-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-02-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-02-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-04-2015
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-06-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-11-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-03-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-04-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-10-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-12-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-01-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-01-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-01-2017
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-02-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-11-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-09-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-02-2020
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

ID: 23168
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL49015.029.14
OMON	NL-OMON23168