

# Coronary angiography after cardiac arrest

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Coronary artery disorders
<b>Study type</b>	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 of 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 successful resuscitation are frequently presented to the ER. Although the resuscitation was successful and circulation was restored, most patients are unconscious and mechanically ventilated. The prognosis of these patients remains poor due to damage to brain and heart. If the EKG shows signs of a large myocardial infarction (STEMI), there is an indication for acute coronary angiography and primary 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 question also arises whether 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 randomised and subject to selection bias. Furthermore several randomised 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 addressing 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 a 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