Coronary angiography after cardiac arrest

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23168

Source
NTR

Brief title
The COACT trial

Health condition

ACS
Cardiac arrest
coronary angiography

Sponsors and support

Primary sponsor: fund=intiator=sponsor
Source(s) of monetary or material Support: fund=intiator=sponsor

Intervention

Outcome measures

Primary outcome

Can an immediate CAG and subsequent PCI in patients after OHCA without STEMI improve 90-days survival compared to a delayed CAG and subsequent PCI (after neurological recovery).

Secondary outcome

-Is there a difference in 90-days survival with good, minor or moderate disability
-Is there a difference in myocardial injury measured by troponine and CK MB as area under the curve between the treatment groups.
-Is there a difference in acute kidney injury according to AKIN criteria between the treatment groups.
-Is there a difference in need for renal replacement therapy between the treatment groups.
-Is there a difference in time to target hypothermia between the treatment groups.
-Is there a difference in duration of inotropic support between the treatment groups.
-Is there a difference in neurological status at ICU discharge between the treatment groups
-Is there a difference in markers of shock: lactate and SVO2 at day 1, 2 en 3 between the treatment groups.
-Is there a difference in the recurrence of ventricular tachycardia needing defibrillation or electrical cardioversion between the treatment groups.
-Is there a difference in the duration of mechanical ventilation between the treatment groups.
-Is there a difference in reason for discontinuation of treatment between the treatment groups.

Study description

Background summary

Rationale: The clinical benefit of acute coronary angiography following return of spontaneous circulation (ROSC) in patients without an ST segment elevation myocardial infarction after out of hospital cardiac arrest (OHCA) is unclear.
Objective: Aim of this study 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. Primary endpoint is survival until 90 days.
Study design: The study is a prospective, randomized controlled, multi-centre study.
Study population: The research population will be recruited from the general patient population presenting with return of spontaneous circulation after out of hospital cardiac arrest without signs of a ST segment elevation myocardial infarction, at the emergency department. A total of 552 consecutive patients will be included.
Intervention (if applicable): The patients will be randomized to either the immediate or delayed coronary angiography and subsequent revascularisation group.
Main study parameters/endpoints: The primary end point of the study is 90-days survival
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, duration of inotropic support, markers of shock,,, recurrence of ventriculair tachycardia, duration of mechanical ventilation and reason for

discontinuation of treatment.

Study objective

Acute coronary angiography and PCI will improve 90 day survival in patients after cardiac arrest and without signs of STEMI.

Study design

01-12-2014 start inrollment
01-12-2017 final inrollment
01-03-2018 end of follow up.

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

-Age > 18
-Comatose patients (Glasgow coma score < 8) with ROSC after OHCA

-Ventricular tachycardia or ventricular fibrillation as initial arrest rhythm. Including patients treated with an AED.

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 prolonged (>30 min) systolic blood pressure < 100 mm Hg at the time of screening.
-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
-Refractory ventricular arrhythmia
-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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2014
Enrollment:	552
Type:	Anticipated

Ethics review

Positive opinion

Date:	19-11-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50572
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4857
NTR-old	NTR4973
CCMO	NL49015.029.14
OMON	NL-OMON50572

Study results