Coronary angiography after cardiac arrest

Gepubliceerd: 19-11-2014 Laatst bijgewerkt: 15-05-2024

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23168

Bron
Nationaal Trial Register

Verkorte titel
The COACT trial

Aandoening

ACS
Cardiac arrest
coronary angiography

Ondersteuning

Primaire sponsor: fund=intiator=sponsor
Overige ondersteuning: fund=intiator=sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

The patients will be randomized to either the immediate or delayed coronary angiography

and subsequent revascularisation group.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

-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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

-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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-12-2014
Aantal proefpersonen:	552
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	19-11-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50572
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten