DIrect or Subacute COronary angiography in out-of-hospital cardiac arrest - a prospective, randomized study

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To investigate whether a strategy of immediate coronary angiography (within 120 minutes) results in improved 30-day survival of out-of-hospital cardiac arrest patients without ST elevation on the ECG, when compared to no immediate coronary...

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

Summary

ID

NL-OMON54636

Source
ToetsingOnline

Brief title
DISCO

Condition

- Coronary artery disorders

Synonym
Cardiac arrest, myocardial infarction

Research involving
Human

Sponsors and support

Primary sponsor: Uppsala University Hospital, department of anesthesiology and intensive

care
Source(s) of monetary or material Support: Uppsala University

Intervention

Keyword: Cardiac arrest, Coronary angiography, Out-of-hospital resuscitation

Outcome measures

Primary outcome

30 day survival

Secondary outcome

- survival with favorable neurologic outcome

- survival to intensive care unit (ICU) discharge, survival to 6 months

- surival with favorable neurologic ouctome at ICU discharge and at 6 months

- cardiac function (ejection fraction) at 72 hours and at 6 months

- neurologic and cognitive dunction, depression, anxiety, quality of life,

fatigue, and relative's situation at 6 months

- hemodynamic parameters during ICU stay

- electrocardiographic findings

Study description

Background summary

Cardiac arrest is a leading cause of death in the Western world. Despite efforts to improve outcome, survival remains poor. In about half of patients, return of spontaneous circulation is achieved, but only about 23% of patients survives to discharge. For the subgroup presenting with ventricular fibrillation as initially observed cardiac rhythm outcome is markedly better, with about 47% surviving to discharge in the Netherlands. Unfortunately, a major cause of death in hospital is poor neurologic functioning related to the period of circulatory arrest.
In a large proportion of patients, the underlying cause of cardiac arrest is an

acute myocardial infarction, resulting from of an occlusion of one of the coronary vessels. This may lead to life threathening cardiac rhythm disorders resulting in cardiac arrest. In case of ST elevation of the ECG obtained after return of spontaneous circulation, we know that the underlying cause of cardiac arrest was indeed an acute myocardiale infarction, and for this subset of patients the treatment of choice is immediate coronary angiography with primary PCI. In contrast, for the subset without ST elevation on the ECG, it is uncertain whether an immediate coronary anigography is helpful to improve outcome. Data from observational studies - prone to selection bias - showed conflicting results. A recently performed, small randomized trial indicated that a strategy of immedicatie coronary angiography did not improve survival when compared to a strategy of delayed coronary angiography. This Dutch study was limited to patients with ventricular fibrillation as initially observed cardiac rhythm and survival was overall very high, limiting inferences to the general out-of-hospital cardiac arrest patient. The findings of this study alone will not result in a class IA recommendation in the guidelines for cardiopulmonary resuscitation. Moreover, questions regarding the impact on heart function and neurologic recovery remain. Therefore, additional studies are eagerly awaited. The DISCO is a large, randomized controlled, European multicenter study that should improve our understanding of the potential value of immediate coronary angiography in resuscitated patients without ST elevation. In the DISCO study, both patients presenting with ventricular fibrillation as well as with other cardiac rhythms (i.e. asystole, pulseless electrical activity) will be included. The primary aim is to investigate whether a strategy of immediate coronary angiography (within 120 minutes) results in improved 30-day survival of out-of-hospital cardiac arrest patients without ST elevation on the ECG, when compared to a strategy without immediate coronary angiography. In the secondary endpoints of the study, specific focus is put on neurologic functioning during and after hospital discharge.

Study objective

To investigate whether a strategy of immediate coronary angiography (within 120 minutes) results in improved 30-day survival of out-of-hospital cardiac arrest patients without ST elevation on the ECG, when compared to no immediate coronary angiography.

Study design

Randomized controlled, international, multicenter trial

Intervention

Acute coronary aniography with - if applicable - coronary revascularization.

Study burden and risks

The risk and burden is related to the coronary angiography. Coronary angiography is a standard part of the workup of cardiac arrest patients and is almost always performed. Risks include bleeding at the insertion point and contrast nephropathy. In the immediate coronary angiography group, patients are unconscious (shortly after resuscitation) and will not be aware of the intervention. After one month, a telephone check-up will be performed and at 6 months an outpatient visit is scheduled including echocardiography.

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

- Witnessed out-of-hospital cardiac arrest
- Return of spontaneous circulation for more than 20 minutes
- Ability to perform coronary angiography within 120 minutes after

randomization

Exclusion criteria

Age < 18 years
Apparent non-cardiac etiology
ST elevation on the initial ECG
Pregnancy
Conscious patients with a Glasgow Coma Scale >8
Terminally ill patients with an expected survival of less than 1 year

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-06-2020
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	17-02-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO Date:	19-05-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	16-11-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	30-11-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
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Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	06-06-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
ClinicalTrials.gov	NCT02309151
CCMO	NL71318.091.19