Direct or subacute coronary angiography in patients with out of hospital cardiac arrest without coma - A prospective randomized study

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To compare major adverse cardiovascular events between non-comatose patients undergoing urgent CAG (within 2 hours after admission) vs. patients who dit not undergo urgent CAG (CAG if indicated after 12-24 hours).

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

Summary

ID

NL-OMON56461

Source
ToetsingOnline

Brief title
DISCO-No-COMA

Condition

- Coronary artery disorders

Synonym
Cardiac arrest, myocardial infarction

Research involving
Human

Sponsors and support

Primary sponsor: Aarhus University Hospital

Source(s) of monetary or material Support: Aarhus University Hospital

Intervention

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

Outcome measures

Primary outcome

Major Adverse Cardiovascular Events (MACE): 30-day mortality, cardiogenic shock, or recurrent cardiac arrest within 30 days from randomization.

Secondary outcome

1. 30-day, 1-year and 5-year mortality.

2. Cardiogenic shock (Lactate>2.5 mmol/l and systolic blood pressure <90 mmHg or need of inotropic or use of mechanical devices (Impella/VA-ECMO/similar) in the waiting time for CAG (after randomization) and within 30 days and 1-year respectively.

3. Recurrent cardiac arrest in the waiting time for CAG (after randomization) and within 30-day and 5-year, respectively.

4. Shock from ICD I the waiting time for CAG (After randomization), within 30 days and 5-year, respectively.

5. Final cardiac arrest cause: Non-cardiac or cardiac, and for cardiac causes further subclassification: Acute Myocardial Infarction, Pulmonary Embolism, Primary Arrhythmia, Aortic Dissection, Other.

6. AMI within 1 year.

7. Readmission with congestive heart failure within 1 year.

8. Proportion revascularized with either PCI or CABG within 30 days and 1 year.

9. Proportion with implantation of ICD within 1 year.

10. Drop in Hgb >=1.86 mmol/l or transfusion of >=2 units of blood within 30 days.

11. Increase in creatinine more than 100% within 30 days.

12. Dialysis within 30 days.

13. Vascular surgery (related to access site) within 30 days.

14. Time from randomization to final diagnosis is established (Evaluated by an endpoint committee)

15. Hospital length of stay.

16. Proportion with cross-over to acute CAG in cohort B.

17. CPC score and mRS score after 30 day and 6-month.

18. EQ-5D-5L score after 30-day and 6-month.

19. GOSE and MOCA score at 6-month.

Study description

Background summary

Out-of-hospital cardiac arrests occur frequently with about 300 cases each week in the Netherlands. The underlying cause of cardiac arrest often is an acute myocardial infarction complicated by life threathening cardiac arrhythmias. An acute myocardial infarction can be recognized by ST segment elevation on the post-resuscitation ECG. After hospital arrival, these patients undergo urgent coronary angiography (CAG), with PCI in case a culprit lesion is identified.
Even in the absence of ST segment elevation, we know that coronary artery disease has often been the cause of cardiac arrest. Therefore, recent (small) studies have investigated whether urgent CAG results in improved survival in comatose post-cardiac arrest patients without ST segment when compared to delayed CAG. This turned out not to be the case; outcomes were not different.
The international randomized DISCO study (Direct or subacute COronary angiography in out-of-hospital cardiac arrest - DISCO) is still ongoing and is expected to provide final evidence on this topic. For non-comatose patients, there is no evidence whatsoever about the diagnostic strategy to be followed.
Therefore, in follow-up of the DISCO study, the randomized DISCO-No-COMA study compares clinical outcomes (MACE) between non-comatose patients (n=1200) without ST elevation who underwent urgent CAG vs. those who did not undergo

urgent CAG.

Study objective

To compare major adverse cardiovascular events between non-comatose patients undergoing urgent CAG (within 2 hours after admission) vs. patients who dit not undergo urgent CAG (CAG if indicated after 12-24 hours).

Study design

Randomized controlled, international, multicenter trial

Intervention

Acute coronary angiography 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. 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
- Possible to perform CAG within 120 minutes of randomization
- Glasgow coma scale >8

Exclusion criteria

- Age < 18 years
- Obvious non-cardiac cause for cardiac arrest
- Terminal illness
- ST elevation myocardial infarction

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):	14-08-2024
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	20-12-2023
Application type:	First submission
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	NCT04876222
CCMO	NL81185.091.23