

Early or late intervention in high risk non-ST elevation acute coronary syndromes

Submission date 22/11/2006	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 22/11/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 13/12/2016	Condition category Circulatory System	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
13407

Study information

Scientific Title
Early or Late Intervention in high risk non-ST elevation Acute coronary syndromes

Acronym

Study objectives

Primary hypothesis:

An immediate invasive approach (immediate angiography and revascularisation when appropriate) results in a reduction of the combined incidence of death, re-infarction or recurrent ischemia at 30 days follow-up.

Secondary hypotheses:

1. An immediate invasive approach (immediate angiography and revascularisation when appropriate) results in a reduction of enzymatic infarct size as assessed by a single troponin T measurement at 72 to 96 hours after admission or at discharge.
2. An immediate invasive approach (immediate angiography and revascularisation when appropriate) results in a higher percentage of patients without a rise in Creatinine Kinase myocardial bands (CKmb) during hospital admission.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Non ST-Elevation Acute Coronary Syndrome (NSTEMI-ACS)

Interventions

Immediate angiography and revascularisation reduces compared to delayed angiography not earlier than 48 hours after admission.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Combined incidence of death, re-infarction and hospitalisation for recurrent ischemia at 30 days follow-up

Key secondary outcome(s)

1. Enzymatic infarct size as assessed by a single cardiac Troponin T, measured at 72 to 96 hours after admission or at discharge
2. The percentage of patients without a rise in CKmb during admission

Completion date

31/12/2008

Eligibility

Key inclusion criteria

Ischemic Chest Pain or Dyspnoe at rest with last attack less than 24 hours with at least two out of three of the following characteristics:

1. Evidence of extensive myocardial ischemia on ElectroCardioGram (ECG): (new) cumulative ST depression more than 5 mm or temporary ST segment elevation in two contiguous leads less than 30 minutes
2. Evidence of myocardial damage: positive troponin (more than 0.05 ng/ml) or myoglobin (more than 150 microg/l) on admission or three hours later or positive CKmb fraction on admission (more than 6% of total CK)
3. Age above 65 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Sex

All

Key exclusion criteria

1. Persistent ST segment elevation
2. Absolute contra-indication for diagnostic angiography
3. Active bleeding
4. Cardiogenic shock
5. Acute posterior infarction
6. Life expectancy less than one year

Date of first enrolment

01/08/2006

Date of final enrolment

31/12/2008

Locations

Countries of recruitment

Netherlands

Study participating centre

Diagram B.V.
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8011 NB

Sponsor information

Organisation

Isala Clinics (Isala klinieken) (Netherlands)

ROR

<https://ror.org/046a2wj10>

Funder(s)

Funder type

Industry

Funder Name

Diagram B.V., Isala Kliniek

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	20/05/2013		Yes	No
Results article	results	17/11/2016		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes