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

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

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.diagram-zwolle.nl

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

13407

Study information

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

Acronym
ELISA-3

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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

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

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

Intervention Type
Procedure/Surgery

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

Secondary outcome measures
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

Overall study start date
01/08/2006

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

Age group
Senior

Sex
Both

Target number of participants
540

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.
Zwolle
Netherlands
8011 NB

Sponsor information

Organisation
Isala Clinics (Isala klinieken) (Netherlands)

Sponsor details
Locatie Weezenlanden
Department of Cardiology
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/046a2wj10

Funder(s)

Funder type
Industry

Funder Name
Diagram B.V., Isala Kliniek

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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