

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

<b>Submission date</b> 22/11/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 22/11/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 13/12/2016	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

**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**

## 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 (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 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 Dyspnoea 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

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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?
<a href="#">Results article</a>	results	20/05/2013		Yes	No
<a href="#">Results article</a>	results	17/11/2016		Yes	No