

ELISA-2 (Early or Late Intervention in unStable Angina)

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| Submission date 12/09/2005 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 12/09/2005 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 05/08/2021 | Condition category 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/Default.aspx>

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NL77, NTR108

Study information

Scientific Title

ELISA-2 (Early or Late Intervention in unStable Angina)

Acronym

ELISA-2

Study objectives

In patients presenting with a non-ST elevation acute coronary syndrome with (new) ST segment depression and/or positive troponin-T, who undergo PCI, treatment with a dexamethason coated stent will reduce the incidence of restenosis at 6 month follow-up angiography.

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)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Unstable angina pectoris, acute coronary syndrome

Interventions

Angiography and Revascularisation (PCI) after 24 hours pre-treatment with Tirofiban compared to Angiography after Pre-Treatment with Clopidogrel in High Risk Patients with Unstable Angina.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Enzymatic infarct size

Secondary outcome measures

1. Enzymatic Infarct Size (LDHQ72)
 2. Hospital Stay - Total duration in hospital in days, including admission and discharge day
- Do Dexamethason-coated Stents Decrease the incidence of Restenosis in patients with an Acute Coronary Syndrome?
3. Clinical endpoints
 - 3.1 Death - Total mortality will be assessed at 30 days follow-up.
 - 3.2 Myocardial Infarction
 - a. Early MI in patients presenting with CKmb > upper limit of normal.
 - b. Early MI in patients presenting with CKmb not exceeding the upper limit of normal
 - c. Late MI in patients whose CKmb has returned to (or has remained) normal.
 - d. MI in patients who underwent CABG.
 - 3.3 Stroke - All (hemorrhagic and non-hemorrhagic) strokes must be confirmed by CT scan examination and after consultation of a neurologist.
 - 3.4 Bleeding
 4. Secondary Efficacy Parameter
 - 4.1 The Tirofiban strategy results in a better patency of the culprit coronary artery before intervention.
 - 4.2 Coronary Angiography. All angiography films will be evaluated by an independent core-laboratory (DIAGRAM, Zwolle, the Netherlands), without access to clinical data.

Overall study start date

01/04/2002

Completion date

01/04/2005

Eligibility**Key inclusion criteria**

At least 2 out of 3 of the following:

1. Ischemic Chest Pain at rest with last attack < 24 hours
2. Evidence of myocardial Ischemia on ECG
3. (New) ST depression > 0,1 mVolt in 2 leads
4. Evidence of myocardial damage
5. Positive Troponin (>0.05 microgr/l) or Myoglobin (>200 microg/l) on admission or 3 hours later
6. Positive CPKmb fraction on admission

Participant type(s)

Patient

Age group

Adult

Sex

Not Specified

Target number of participants

330

Total final enrolment

328

Key exclusion criteria

1. Aged <50 or >80 years
2. Persistent ST segment elevation
3. Cardiogenic Shock or pulmonary edema
4. Myocardial ischemia precipitated by non-cardiac condition (anemia, hyperthyroidism)
5. PTCA within previous 6 months
6. Renal failure/Liver failure

Date of first enrolment

01/04/2002

Date of final enrolment

01/04/2005

Locations**Countries of recruitment**

Netherlands

Study participating centre

Diagram B.V. Zwolle

Zwolle

Netherlands

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Sponsor information**Organisation**

Isala klinieken, locatie Weezenlanden, Dept of Cardiology (The Netherlands)

Sponsor details

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Sponsor type

Not defined

ROR

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

Funder(s)

Funder type

Not defined

Funder Name

Not provided at time of registration

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 | | 01/06/2006 | 05/08/2021 | Yes | No |