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

Submission date	Recruitment status	[_] Prospectively registered
12/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/08/2021	Circulatory System	

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 returmed 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)

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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