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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24053

Source
Nationaal Trial Register

Brief title
ELISA-2

Health condition

Acute coronary syndrome.

Sponsors and support

Primary sponsor: AWJ van ¡¦t Hof, MD, PhD
Dept of Cardiology
Isala Klinieken, locatie Weezenlanden
Groot Wezenland 20
8011 JW, Zwolle, the Netherlands

Intervention

Outcome measures

Primary outcome

The Tirofiban strategy results in a smaller enzymatic infarct size, compared to the Clopidogrel strategy.

Secondary outcome

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

2.Secondary Efficacy Parameter

The Tirofiban strategy results in a better patency of the culprit coronary artery before intervention.

2.1Coronary Angiography

All angiography films will be evaluated by an independent core-laboratory (DIAGRAM, Zwolle, the Netherlands), without access to clinical data.

Study description

Background summary

This is a randomised, open, single center study. It is designed to compare 2 treatment strategies in patients with a non-ST elevation acute coronary syndrome and (new) ST segment depression and/or positive troponin-T. It will investigate whether angiography and revascularisation with (24 hours) pre-treatment with a glycoprotein 2b/3a receptor blocker (Tirofiban strategy), reduces enzymatic infarct size compared to pre-treatment with a platelet aggregation inhibitor (Clopidogrel strategy).

Angiographic substudy:

Do Dexamethason-coated Stents Decrease the incidence of Restenosis in patients with an Acute Coronary Syndrome?

Patients will be randomised to blinded stent designs. Neither the operator, nor the patient will know whether the delivered stent is Dexamethason coated or non-coated.

Study objective

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.

Study design

N/A

Intervention

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.

Contacts

Public
Diagram B.V. Zwolle

Dokter Stolteweg 96

J. Klijn
Dokter Stolteweg 96

Zwolle 8025 AZ
The Netherlands
+31 (0)38 4262997
Scientific
Diagram B.V. Zwolle
Dokter Stolteweg 96

J. Klijn
Dokter Stolteweg 96

Zwolle 8025 AZ
The Netherlands
+31 (0)38 4262997

Eligibility criteria

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:

(New) ST depression > 0,1 mVolt in 2 leads;

3. Evidence of myocardial damage:

Positive Troponin (>0.05 microgr/l) or Myoglobin (>200 microg/l) on admission or 3 hours later or;

4. Positive CPKmb fraction on admission.

Exclusion criteria

1. Age <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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2002
Enrollment:	330
Type:	Actual

Ethics review

Positive opinion

Date:	02-08-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL77
NTR-old	NTR108
Other	:
ISRCTN	ISRCTN87763194

Study results

Summary results
Eur Heart J. 2006 Jun;27(12):1401-7. Epub 2006 May 8.