Early or Late Intervention in high risk non ST elevation Acute Coronary Syndromes.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26567

Source
NTR

Brief title
Elisa-3

Health condition

high risk non-ST elevation acute coronary syndrome patients

Sponsors and support

Primary sponsor: Diagram B.V.
v. Nahuysplein 6
8011 NB Zwolle
The Netherlands
Source(s) of monetary or material Support: unk

Intervention

Outcome measures

Primary outcome

Combined incidence of death, re-infarction and hospitalization for recurrent ischemia at 30 days follow-up.

Secondary outcome

1. Enzymatic Infarct Size as assessed by a single cardiac Troponin T, measured at 72-96 hours after admission or at discharge;
2. The percentage of patients without a rise in CKmb during admission.

Study description

Background summary

It concerns a prospective, randomized, multi center trial, comparing immediate vs delayed intervention in patients with non ST elevation myocardial infarction who present with extensive ST segment depression. The primary endpoint is the combined incidence of death, re-infarction and hospitalization for recurrent ischemia at 30 days follow-up.

Study objective

Primary

1. An immediate invasive approach (immediate angiography and revascularization when appropriate) results in a reduction of the combined incidence of death, re-infarction or recurrent ischemia at 30 days follow-up.
Secondary

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 72-96 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 CKmb during hospital admission.

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

Ischemic Chest Pain or Dyspnoe at rest with last attack < 24 hours with at least 2 out of 3 of the following characteristics:
1. Evidence of extensive myocardial Ischemia on ECG:
i. (New) Cumulative ST depression > 5 mm or
ii. Temporary ST segment elevation in 2 contiguous leads < 30 minutes;
2. Evidence of myocardial damage:
i. Positive Troponin (>0.05 ng/ml) or Myoglobin (>150 microg/l) on admission or 3 hours later or
ii. Positive CKmb fraction on admission (>6% of total CK);
3. Age above 65 years.

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. Live expectancy less than 1 year.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2006
Enrollment:	540
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL731
NTR-old	NTR741
Other	: 13407
ISRCTN	ISRCTN39230163

Study results

Summary results

1. van 't Hof AW, de Vries ST, Dambrink JH, Miedema K, Suryapranata H, Hoorntje JC, Gosselink AT, Zijlstra F, de Boer MJ. A comparison of two invasive strategies in patients with non-ST elevation acute coronary syndromes: results of the Early or Late Intervention in unStable Angina (ELISA) pilot study. 2b/3a upstream therapy and acute coronary syndromes. Eur Heart J 2003;24:1401-5.
2. Savonitto S, Cohen MG, Politi A, Hudson MP, Kong DF, Huang Y, et al. Extent of ST-segment depression and cardiac events in non-ST-segment elevation acute coronary syndromes. Eur Heart J 2005;26:2106-2113.
3. de Araujo Goncalves P, Ferreira J, Aguiar C, Seabra-Gomes R. TIMI, PURSUIT, and GRACE risk scores: sustained prognostic value and interaction with revascularization in NSTE-ACS. Eur Heart J 2005 26:865-72.
4. Neumann FJ, Kastrati A, Pogatsa-Murray G, Mehilli J, Bollwein H, Bestehorn HP, et al. Evaluation of prolonged antithrombotic pretreatment ("cooling-off" strategy) before intervention in patients with unstable coronary syndromes: a randomized controlled trial. JAMA 2003;290:1593-1599.
5. Mehta SR, Cannon CP, Fox KA et al. Routine vs selective invasive strategies in patients with acute coronary syndromes: a collaborative meta-analysis of randomized trials. JAMA 2005;293:2908-17.
6. Ripa RS, Holmvang L, Maynard C. Sejersten M, Clemmensen P, Grande P, et al. Consideration of the total ST segment deviation on the initial ECG for predicting final acute posterior myocardial infarct size in patients with maximum ST segment deviationas depression in leads V1 through V3. A FRISC-II substudy. J Electrocardiol 2005;38:180-186.
7. Buiatti E, Barchielli A, Marchionni N, Balzi D, Carrabba N, Valente S, et al. Determinants of treatment strategies and survival in acute myocardial infarction: a population-based study in the Florence district, Italy: Results of the acute myocardial infarction Florence registry (AMI-Florence). Eur Heart J 2003;24:1195-1203.