

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

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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...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26567

Bron

Nationaal Trial Register

Verkorte titel

Elisa-3

Aandoening

high risk non-ST elevation acute coronary syndrome patients

Ondersteuning

Primaire sponsor: Diagram B.V.

v. Nahuysplein 6

8011 NB Zwolle

The Netherlands

Overige ondersteuning: unk

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Blinding:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-08-2006
Aantal proefpersonen:	540
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing	
Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL731
NTR-old	NTR741
Ander register	: 13407
ISRCTN	ISRCTN39230163

Resultaten

Samenvatting resultaten

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 NSTEMI-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 deviation as 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.