Invasive versus Conservative Treatment in Unstable coronary Syndromes.

No registrations found.

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

Summary

ID

NL-OMON23333

Source
NTR

Brief title
ICTUS

Health condition

Acute coronary syndromes

Sponsors and support

Primary sponsor: The ICTUS trial is supported by educational grants from Eli Lilly, Sanofi-Synthelabo, Aventis, Pfizer, and Medtronic.
Source(s) of monetary or material Support: The ICTUS trial is supported by the Interuniversity Cardiology Institute of the Netherlands (ICIN) and the Working Group on Cardiovascular Research in the Netherlands (WCN). ICIN, Catharijnesingel 52, Postbus 19258, 3501 DG Utrecht

Intervention

Outcome measures

Primary outcome

The primary end point is

1. A composite of death;

2. Nonfatal myocardial infarction;

3. Or rehospitalization for anginal symptoms within one year after randomization.

Secondary outcome

1. The occurrence of the components of the primary endpoint;

2. The occurrence of death or myocardial infarction;

3. A percutaneous coronary intervention;

4. Coronary artery bypass grafting;

5. Functional status after one, six, and twelve months;

6. Two, three and five years follow-up.

Study description

Background summary

N/A

Study objective

An early invasive strategy is superior to a selectively invasive strategy for patients who have acute coronary syndromes
without ST-segment elevation and with an elevated cardiac troponin T level.

Intervention

Against a background of optimized medical therapy patients are randomized between an early invasive strategy or a selective invasive strategy.
The early invasive strategy include angiography within 24 to 48 hours after randomization and revascularization when appropriate.
The selective invasive strategy include medical stabilization, with angiography and revascularization only in case of refractory angina or significant ischemia on the pre discharge exercise test.

Contacts

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Eligibility criteria

Inclusion criteria

1. Symptoms of ischemia that were increasing or occurred at rest, with the last episode occurring no more than 24 hours before randomization;
- an elevated cardiac troponin T level (≥0.03µg per liter);
2. and either ischemic changes as assessed by electrocardiography (defined as ST-segment depression or transient ST-segment elevation exceeding 0.05 mV,
3. or T-wave inversion of ≥0.2 mV in two contiguous leads)
4. or a documented history of coronary artery disease as evidenced by previous myocardial infarction,
5. findings on previous coronary angiography, or a positive exercise test.

Exclusion criteria

1. Age younger than 18 years or older than 80 years;

2. Myocardial infarction with ST-segment elevation in the past 48 hours;

3. An indication for primary percutaneous coronary intervention or fibrinolytic therapy,
- hemodynamic instability or overt congestive heart failure;

4. The use of oral anticoagulant drugs in the past 7 days,;
5. Fibrinolytic treatment within the past 96 hours;

6. Percutaneous coronary intervention within the past 14 days;

7. A contraindication to treatment with percutaneous coronary intervention or glycoprotein IIb/IIIa inhibitors;

8. Recent trauma or risk of bleeding;

9. Hypertension despite treatment and weight greater than 120 kg.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2001
Enrollment:	1200
Type:	Actual

Ethics review

Positive opinion

Date:	12-12-2005
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	NL401
NTR-old	NTR442
Other	: N/A
ISRCTN	ISRCTN82153174

Study results

Summary results
de Winter RJ, Windhausen F, Cornel JH et al. Early invasive versus selectively invasive management for acute coronary syndromes. N Engl J Med. 2005; 353(11): 1095-104