

Invasive versus Conservative Treatment in Unstable coronary Syndromes

Submission date 27/01/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 27/01/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 15/01/2015	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NTR442

Study information

Scientific Title
Invasive versus Conservative Treatment in Unstable coronary Syndromes

Acronym

ICTUS

Study objectives

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.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from local medical ethics committee

Study design

Multicentre randomised open label active controlled parallel group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Acute coronary syndrome

Interventions

Against a background of optimized medical therapy patients are randomized between an early invasive strategy or a selective invasive strategy.

The early invasive strategy includes angiography within 24 to 48 hours after randomization and revascularization when appropriate.

The selective invasive strategy includes medical stabilization, with angiography and revascularization only in case of refractory angina or significant ischemia on the pre-discharge exercise test.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Within one year after randomisation, a composite of:

1. Death
2. Non-fatal myocardial infarction
3. Rehospitalization for anginal symptoms

Key secondary outcome(s)

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

Completion date

01/09/2008

Eligibility

Key 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
2. An elevated cardiac troponin T level (≥ 0.03 ug per litre)
3. Either ischemic changes as assessed by electrocardiography defined as ST-segment depression or transient ST-segment elevation exceeding 0.05 mV
4. Or T-wave inversion of ≥ 0.2 mV in two contiguous leads
5. Or a documented history of coronary artery disease as evidenced by previous myocardial infarction
6. Findings on previous coronary angiography, or a positive exercise test

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key 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
4. Hemodynamic instability or overt congestive heart failure
5. The use of oral anticoagulant drugs in the past 7 days
6. Fibrinolytic treatment within the past 96 hours
7. Percutaneous coronary intervention within the past 14 days
8. A contraindication to treatment with percutaneous coronary intervention or glycoprotein IIb/IIIa inhibitors
9. Recent trauma or risk of bleeding
10. Hypertension despite treatment and weight greater than 120 kg

Date of first enrolment

01/07/2001

Date of final enrolment

01/09/2008

Locations

Countries of recruitment

Netherlands

Study participating centre**Academic Medical Center**

Amsterdam

Netherlands

1100 DD

Sponsor information

Organisation

Interuniversity Cardiology Institute of the Netherlands (ICIN) (Netherlands)

ROR

<https://ror.org/01mh6b283>

Funder(s)

Funder type

Industry

Funder Name

Medtronic BV (Netherlands)

Funder Name

Pfizer (Netherlands)

Alternative Name(s)

Pfizer Inc., Pfizer Consumer Healthcare, Davis, Charles Pfizer & Company, Warner-Lambert, King Pharmaceuticals, Wyeth Pharmaceuticals, Seagen, Pfizer Inc

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Funder Name

Sanofi-Aventis (Netherlands)

Funder Name

Eli Lilly (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/09/2005		Yes	No
Results article	results	10/03/2007		Yes	No
Results article	results	23/02/2008		Yes	No
Results article	results	02/03/2010		Yes	No
Results article	substudy results	15/03/2014		Yes	No
Other publications	collaborative analysis	31/01/2012		Yes	No
Other publications	collaborative analysis	01/02/2012		Yes	No