ISRCTN82153174 https://doi.org/10.1186/ISRCTN82153174

Invasive versus Conservative Treatment in Unstable coronary Syndromes

Submission date	Recruitment status	[_] Prospectively registered
27/01/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/01/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
15/01/2015	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
Within one year after randomisation, a composite of:
1. Death
2. Non-fatal myocardial infarction
3. Rehospitalization for anginal symptoms

Secondary outcome measures
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

Overall study start date
01/07/2001

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

Age group
Adult

Sex
Both

Target number of participants
1200

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)

Sponsor details

PO Box 19258
Utrecht
Netherlands
3501 DG

Sponsor type
University/education

Website
http://www.icin.nl

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

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

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
Other publications	collaborative analysis	31/01/2012		Yes	No
Other publications	collaborative analysis	01/02/2012		Yes	No
Results article	substudy results	15/03/2014		Yes	No