Adenosine Administration during and after Primary percutaneous coronary intervention in acute myocardial infarction – a Randomized Controlled Trial (ADAPT).

No registrations found.

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

Summary

ID

NL-OMON22898

Source
Nationaal Trial Register

Brief title
ADAPT

Health condition

1. Percutaneous coronary intervention;

2. Myocardial infarction;

3. Reperfusion therapy.

Sponsors and support

Primary sponsor: University Medical Center Groningen,
Thoraxcenter, Dept Cardiology.
Source(s) of monetary or material Support: University Medical Center Groningen,
Thoraxcenter, Dept Cardiology.

Intervention

Outcome measures

Primary outcome

Residual ST-segment deviation at 30 to 60 minutes after the procedure.

Secondary outcome

1. Myocardial blush grade;

2. ST-segment deviation resolution;

3. Enzymatic infarct size;

4. Distal embolization on coronary angiography;

5. Post-procedural TIMI flow;

6. Clinical outcome at 30 days and 12 months.

Study description

Background summary

Background: Primary percutaneous coronary intervention (PCI) has been associated with a high incidence of diminished myocardial perfusion, despite a patent epicardial vessel. This so-called no-reflow phenomenon, can result in larger infarct size, less recovery of left ventricular ejection fraction, and increased mortality.
Objectives: The primary objective is to investigate the effect of intracoronary (IC) injection of adenosine on myocardial perfusion. We hypothesize that IC injection of adenosine during and after PCI will reduce residual ST-segment deviation at 30 to 60 minutes after the procedure by 25%. Secondary objectives include the investigation of the impact of adenosine in improving procedural outcome, as assessed by coronary angiography, electrocardiography and clinical outcome.

Study design: The study is a single-center, prospective, randomized trial with blinded evaluation of endpoints.

Study population: All patients with acute myocardial infarction and candidates for primary PCI admitted to the University Medical Center of Groningen are considered for participation in the study. The planned inclusion of the study involves 450 patients.

Intervention: The primary treatment is thrombus aspiration followed by stent implantation. During and after PCI, patients are assigned to treatment with IC injections of adenosine or placebo.
Main study outcome parameters: The primary outcome parameter is residual ST-segment deviation at 30 to 60 minutes after the procedure. Secondary outcome parameters are: post-procedural TIMI flow, myocardial blush grade and distal embolization on coronary angiography, ST-segment deviation resolution, enzymatic infarct size and clinical outcome at 30 days and 12 months.

Risks associated with participation: Currently available clinical evidence documents a risk profile of additional IC injections of adenosine comparable to a standard PCI procedure.

Implications: If IC adenosine injections lead to a significant reduction in the amount of residual ST-segment deviation, it will give support to the use of IC adenosine as part of the standard approach in patients with AMI.

Study objective

Intracoronary adenosine injections will lead to a significant reduction in the amount of residual ST-segment deviation.

Intervention

Intracoronary adenosine injection versus placebo.

Contacts

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Eligibility criteria

Inclusion criteria

1. A diagnosis of acute MI defined by chest pain suggestive for myocardial ischemia for at least 30 minutes, with a time from onset of symptoms of less than 12 hours, before hospital admission.

2. An ECG with ST- segment deviation of more than 0.1 mV in 2 or more leads.

3. Thrombus aspiration performed.

4. Verbal followed by written informed consent.

5. 18 years or older.

Exclusion criteria

1. Need for emergency coronary artery bypass grafting (CABG).

2. Presence of cardiogenic shock.

3. Known existence of a life-threatening disease with a life expectancy of less than 6 months.

4. Receiving pharmacotherapy for chronic obstructive pulmonary disease (COPD).

5. Inability to provide informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-08-2007
Enrollment:	450
Type:	Actual

Ethics review

Positive opinion

Date:	27-09-2007
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	NL1040
NTR-old	NTR1073
Other	METC Groningen : METc 2007/110
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A