High dose adenosine in acute myocardial infarction study

Published: 21-12-2007
Last updated: 10-05-2024

This study is designed to investigate the limiting effect on infarct size of high dose intravenous adenosine during primary angioplasty

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON31451

Source
ToetsingOnline

Brief title
Hammer 2

Condition

- Coronary artery disorders
- Cardiac therapeutic procedures
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
acute myocardial infarction, heart attack

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Stichting Hartcentrum Twente

Intervention

Keyword: Adenosine, Myocardial Infarction, Percutaneous Coronary Intervention

Outcome measures

Primary outcome

Infarct size and no-reflow zone on CE-MRI 3 months after index PCI

Secondary outcome

ST-segment resolution, angiographic parameters, enzymatic infarctsize,

ventricular function, clinical parameters

Study description

Background summary

Patients with acute myocardial infarction are best treated with recanalization of the occluded coronary artery by primary angioplasty. Of these patients, 25-30% has signs of incomplete or absent microvascular coronary reflow. The exact cause is unknown but it is complicated by a high morbidity and mortality rate. Adenosine has shown to ameliorate coronary flow. Studies to limit infarct size with adenosine are equivocal, but are mainly performed with low dose.

Study objective

This study is designed to investigate the limiting effect on infarct size of high dose intravenous adenosine during primary angioplasty

Study design

Randomized study comparing standard care to standard care plus intravenous adenosine during primary PCI in patient with acute myocardial infarction.

Intervention

Intravenous Adenosine 140 µg/kg per min during the course of the PCI (appr. 1 hour)

Study burden and risks

Side effects of Adenosine: atrioventricular block and brochospasm: small risk and terminated quickly due to short half-lifetime of adenosine: less than 10 seconds.
Side effects of MRI contrast agent (Gadolinium): allergic reaction: small risk and well treated with antihistaminica and corticosteroids.

Contacts

Public
Medisch Spectrum Twente

Haaksbergerstraat 55
7513 ER
NL
Scientific
Medisch Spectrum Twente

Haaksbergerstraat 55
7513 ER
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients with acute myocardial infarction with clinical indication for primary PCI.
Symptoms of myocardial ischemia less then 6 hours (12 hours in case of anterior infarction with persistent complaints).

Exclusion criteria

history of myocardial infarction
history of heart surgery
obstructive lungdisease
second degree AV-block.
pregnant women
contra-indication for MRI
impossibility to give informed consent

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-09-2008
Enrollment:	80
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Adenosine
Generic name:	Adenosine
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	21-12-2007
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	21-06-2010
Application type:	Amendment
Review commission:	METC Twente (Enschede)

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
EudraCT	EUCTR2007-003611-31-NL
CCMO	NL19151.044.07