Coronary versus Intravenous abCiximab administration during Emergency Reperfusion Of ST-segment elevation myocardial infarction - the CICERO trial

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To investigate whether IC administration of abciximab during primary PCI is superior to IV administration in improving myocardial perfusion in patients with STEMI.

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

Summary

ID

NL-OMON32667

Source
ToetsingOnline

Brief title
CICERO

Condition

- Coronary artery disorders

Synonym
acute myocardial infarction, heart attack

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: abciximab, intracoronary use, primary percutaneous coronary intervention, ST-segment elevation myocardial infarction

Outcome measures

Primary outcome

The primary end point is >70% ST-segment elevation resolution, a marker of

myocardial perfusion.

Secondary outcome

Secondary end points are electrocardiographic and angiographic measures of

myocardial reperfusion, infarct size, and clinical outcome at 30 days and 1

year.

Study description

Background summary

Intravenous (IV) administration of abciximab during primary percutaneous coronary intervention (PCI) plays an important role in the treatment of patients with ST-segment elevation myocardial infarction (STEMI). There is, however, still a high incidence of diminished post-procedural myocardial perfusion, which is associated with poorer clinical outcomes. Recent small-scale studies have indicated that intracoronary (IC) administration of abciximab instead of the (IV) route is associated with improved post-procedural myocardial perfusion.

Study objective

To investigate whether IC administration of abciximab during primary PCI is superior to IV administration in improving myocardial perfusion in patients with STEMI.

Study design

The study is a single-center, prospective, randomized trial with blinded

evaluation of endpoints.

Intervention

During the PCI procedure patients are randomised to receive weight-adjusted abciximab either through the IC or IV route.

Study burden and risks

Currently available clinical evidence documents a risk profile of IC administration of abciximab comparable to IV administration. IC administration of abciximab is not associated with any treatment delay or additional exposure to radiation during PCI. No additional visits or tests are needed except for a questionnaire and/or contact through telephone to assess clinical outcomes. If IC administration of abciximab is superior to IV administration, this finding will give support to incorporating IC use of abciximab into the standard treatment regimen during primary PCI.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
9700 RB Groningen, Postbus 30.001
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
9700 RB Groningen, Postbus 30.001
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- a diagnosis of STEMI defined by
a. chest pain suggestive for myocardial ischemia for at least 30 minutes before hospital admission
b. time from onset of symptoms of less than 12 hours
c. ECG with ST-segment deviation of more than 0.1 mV in 2 or more leads
- primary PCI performed
- verbal followed by written informed consent

Exclusion criteria

-rescue PCI after thrombolytic therapy
-need for emergency coronary artery bypass grafting
-presence of cardiogenic shock
-known existence of a life-threatening disease with a life expectancy of less than 6 months
-inability to provide informed consent
-age below 18 years
-Contra-indications for the use of abciximab (active internal bleeding, history of stroke within 2 years, recent major surgery or intracranial or intraspinal trauma or surgery within 2 months, intracranial neoplasm, arteriovenous malformation or aneurysm, bleeding diathesis, severe uncontrolled hypertension, thrombocytopenia, vasculitis, hypertensie or diabetic retinopathy, severe liver or kidney failure, and hypersensitivity to murine proteins).

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-09-2008
Enrollment:	530
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	ReoPro
Generic name:	abciximab
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	29-07-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	11-11-2009
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	EUCTR2008-004485-12-NL
CCMO	NL24305.042.08