Microvascular Dysfunction in Acute Myocardial Infarction and its Relation to Outcome.

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1) To evaluate absolute myocardial blood flow and resistance over time in the acute and sub-acute phase of myocardial infarction2) To correlate these parameters to preservation of left ventricular function and long-term outcome.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational invasive

Summary

ID

NL-OMON35137

Source
ToetsingOnline

Brief title
Microvascular dysfunction in acute myocardial infarction.

Condition

- Cardiac disorders, signs and symptoms NEC

Synonym
No reflow phenomenon after acute myocardial infarction. Myocardial perfusion after heart attack.

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Stichting Vrienden van het Hart in Zuidoost-

Brabant.

Intervention

Keyword: Acute myocardial infarction, Coronary blood flow, Microvascular dysfunction, Microvascular resistance

Outcome measures

Primary outcome

Absolute coronary and myocardial blood flow and absolute resistance after

successful primary PCI amd after 3-5 days.

Secondary outcome

- Left ventricular function determined by echocardiography immediately after

successful primary PCI and after 3-5 days.

- Viability of the myocardium (or absence of viability) determined by MRI 3-5

days after the acute phase.

Study description

Background summary

Although microvascular dysfunction (no reflow) is often present after acute myocardial infarction, little is known about differences in different patients and about recovery in the first days after myocardial infarction. Even less is known about the consequences for left ventricular function on the long-term.

Study objective

1) To evaluate absolute myocardial blood flow and resistance over time in the acute and sub-acute phase of myocardial infarction
2) To correlate these parameters to preservation of left ventricular function and long-term outcome.

Study design

Open, mono-center, unblinded study.

Study burden and risks

1) After successful primary PCI, the patients stays in the catheterization laboratory for another 20 minutes to perform the measurements of blood flow and resistance.

2) After 3-5 days, a second catheterization will be performed with the physiologic measurements. In approximately 50% of the patients the is an extra investigation; for the other 50%, this exam is replacing the catheterization which would have been performed otherwise after 2 to 3 weeks.

3)

4)

5)

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Acute myocardial infarction presenting at the cath lab within 12 hours of onset of pain.

Exclusion criteria

Instability of the patient after primary percutaneous coronary intervention.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-05-2012
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO

Date:	15-12-2011
Application type:	First submission

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
CCMO	NL37938.060.11