Detection of cardiac fibrosis by LGE MRI and circulating biomarkers in patients with myocardial infarction.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Myocardial disorders
Study type	Observational invasive

Summary

ID

NL-OMON44735

Source
ToetsingOnline

Brief title
DEFI-MI

Condition

- Myocardial disorders

Synonym
myocardial infarction

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Biomarkers, Cardiac remodeling, Fibrosis, Heart failure

Outcome measures

Primary outcome

- Cardiac fibrosis determined by contrast MRI at 4-6 months after myocardial infarction.

- Circulating biomarkers (related to fibrosis) at 4-6 months after myocardial infarction.

Secondary outcome

- Circulating biomarkers (related to fibrosis) at other time points.

- New circulating biomarkers (related to fibrosis and cardiac function)

- Cardiac function

- Death

- Composite endpoint of non-fatal myocardial infarction, stroke, cardiovascular hospitalisation or cardiovascular death.

- Heart failure

- Fibrosis determined with new MRI techniques

Study description

Background summary

Cardiac adverse remodeling takes place in almost every cardiac disease. A main determinant of the adverse remodeling is the deposition of connective tissue in the heart: fibrosis. Fibrosis results in a reduced pump function and an increased susceptibility to arrhythmias. Early assessment of the adverse cardiac remodeling is of particular interest for risk stratification and adjustment of therapy in cardiac patients.

In the clinics, contrast-based MRI is used to determine cardiac fibrosis. Unfortunately, with this technique only larger patches of fibrosis can be observed. Therefore, new MRI techniques are currently developed to improve the detection of cardiac fibrosis.
In the last decade there is also increasing interest in circulating biomarkers; molecules that reflect biological processes which are detectable in the circulation. During fibrosis formation, specific fibrotic biomarkers are released in the blood stream. However, there is only scarce knowledge about the relation between these biomarkers and cardiac fibrosis. In addition to the diagnostic tool of biomarkers, biomarkers may also have a prognostic value. Recently, new potential biomarkers have been identified by the Experimental Cardiology Department (UMC Utrecht) that might be related to the progression of heart failure after a myocardial infarction.

Study objective

The primary objective of this study is to investigate whether circulating fibrotic biomarkers are related to the amount of cardiac fibrosis as determined by MRI in patients. Secondarily, this study aims to investigate whether these biomarkers are related to cardiac function and the prognosis of the MI patients.
In addition, this study serves as a pilot to identify new circulating biomarkers that are associated with fibrosis and cardiac function. Also the predictive and prognostic value of these biomarkers is investigated.
Next to the biomarker investigation, this study is used as pilot-study to investigate promising new MRI techniques that may be used for fibrosis detection. These new MRI techniques are compared to the contrast-based MRI technique.

Study design

Patients with an acute myocardial infarction are followed in time (78 patients). Blood is drawn at four time points to evaluate biomarker levels. At three time points, the patient undergoes MRI and echocardiography to evaluate the cardiac function and cardiac fibrosis.

Study burden and risks

Burden:
For study purposes, the subjects will come back to the UMC Utrecht twice. The total burden for the subjects will be ± 5 hours (3 extra MRIs, one extra echo, and blood withdrawal). The subject may experience laying down without movement and the small space in the MRI as a burden.

Risks:
There are hardly any risks associated with study participation. All study

procedures are according to standard procedures in the UMC Utrecht and are also used in daily practice. The possible risks are related to the MRI: claustrophobia, kidney toxicity, and a reaction against the contrast agent.

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

Subject is diagnosed with acute myocardial infarction.
Subject is 18 years or older.

Exclusion criteria

Subject with known prior acute myocardial infarction, cardiac surgery, or valvular diseases.
Subject is implanted with MRI incompatible prostheses or devices.
Subject has an indication for implantable cardio defibrillator.
Subject is in a condition that alters the collagen turnover.
Subject underwent recent trauma or surgery in the last 6 months.
Subject is diagnosed with kidney failure.
Subject is known with an allergy against gadolinium-based contrast agents.
Subject is familiar with claustrophobia.
Subject is pregnant or has given birth within the past 90 days.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-03-2014
Enrollment:	78
Type:	Actual

Ethics review

Approved WMO Date:	12-11-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	14-08-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO	

Date:	29-03-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	20-12-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL45241.041.13