Feasibility of Magnetic Resonance Imaging for the direct detection of myocardial fibrosis

Published: 04-09-2012
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The feasibility of direct-detection of fibrotic tissue will be assessed in patients with a healed myocardial infarction and in patients with cardiomyopathy using LGE as reference standard.

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

Summary

ID

NL-OMON41279

Source
ToetsingOnline

Brief title
Direct detection of myocardial fibrosis using MRI

Condition

- Myocardial disorders

Synonym
cardiomyopathy, heart attack, 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: cardiomyopathy, fibrosis, Magnetic Resonance Imaging (MRI), myocardial infaction

Outcome measures

Primary outcome

The primary endpoint of this study is the fraction of myocardial fibrosis on

LGE images (reference standard), which are detected on direct MR fibrosis

images.

Secondary outcome

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Study description

Background summary

The deposition of fibrosis after a myocardial infarction and in patients with cardiomyopathy decreases the contractility of the heart and may cause arrhythmias. Late gadolinium enhancement (LGE) Magnetic Resonance Imaging (MRI) is frequently used to evaluate the presence and extent of myocardial fibrosis, but its use increases scan time duration and may cause allergic reactions. Direct-detection of myocardial fibrosis using MRI is free from these limitations.

Study objective

The feasibility of direct-detection of fibrotic tissue will be assessed in patients with a healed myocardial infarction and in patients with cardiomyopathy using LGE as reference standard.

Study design

Cross-sectional diagnostic study.

Study burden and risks

There are minimal risks regarding the use of gadolinium contrast. All subjects

will be screened on allergy for contrastagents and the renal function will be assessed if unknown. Furthermore, no short and long term adverse effects of the MRI scanner on the human body are known.

Only in patients with cardiomyopathy and healthy volunteers (diffuse fibrosis), 2 ml blood will be withdrawn from the intravenous infusion that will be used for administration of the MR contrast agent. Therefore the additional risk is negligible,

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

Treatment group:

- 18 years or older
- previous history of myocardial infarction
- cardiomyopathy
- eligible to give informed consent
Control group:
- age-matched healthy controls
- eligible to give informed consent

Exclusion criteria

- pregnancy or possible pregnancy
- lactation
- documented allergic reaction to gadolinium
- subjects with impaired renal function (severe renal insufficiency, GFR < 30 ml/min/1.73m2)
- impossibility to undergo a MRI scan (determined by using the standard contraindications for MR imaging as used for clinical purposes)

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-07-2013
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO Date:	04-09-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	29-10-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	25-02-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	28-12-2015
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	NL41282.041.12