Feasibility of gadofosveset-enhanced 3.0T cardiac MRI: quantitative comparision with non-enhanced cardiac MRI at 3.0T and 1.5T.

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To study the feasiblity of cardiac MRI at 3T and the potential benefits of the intravascular contrast agent gadofosveset for studying and quantifiaction of heart function and -perfusion.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Observational invasive

Summary

ID

NL-OMON30231

Source
ToetsingOnline

Brief title
gadofosveset-enhanced cardiac MRI at 3.0T

Condition

- Heart failures
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
cardiac failure, ischemic heart disease

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Ziekenhuis Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: 3.0T, cardiac MRI, contrast agents, gadofosveset

Outcome measures

Primary outcome

differences in objective and subjective MRI-image parameters between 1.5T and

3T (artefacts, signal-to-maise ratio, signal and contrast before, during and

after administration of contrast agent, subjective image quality, location and

extent of contrast agent uptake in the wall of the left ventricle).

Secondary outcome

not applicable

Study description

Background summary

Non-invasive diagnosis of cardiovascular diseases is strongly emerging.
Intra-arterial digital subtraction angiography used to be the standard of reference for many clinical indications, but nowadays newer techniques like echo-doppler, computer tomography (CT) and magnetic resonance imaging (MRI) are more widely used. The latter, MRI, is currently considered to be the standard of reference for studying heart function and size of myocardial infarctions.
Untill now, most cardiac MR studies have been performed at 1.5T MRI scanners. Recently, 3T MRI scanners have become clinically available. At high field strengths higher spatial resolution and shorter scan duration can be achieved. Additionally, better visualization of myocardial perfusion might be obtained at 3T because of altered relaxivity of contrast agents at this field strength.
A major disadvantage of 3T MRI scanners is a the occurence of artefacts due to magnetic field inhomogeneities. However, a recent study demonstrated a beneficial effect of intravascular contrast agents: artefacts were reduced at 3T when using the intravascular agent gadomer-17. In our study we will use Gadofosveset, an intravascular albumin binding contrast agent (reversible binding). It has a longer intravascular half life and a higher relaxivity compared to other, extravascular contrast agents. This results in higher signal

intensity, even when using a relatively low dose of the contrast agent.

Study objective

To study the feasiblity of cardiac MRI at 3T and the potential benefits of the intravascular contrast agent gadofosveset for studying and quantifiaction of heart function and -perfusion.

Study design

In this pilot study cardiac MRI at 1.5T and 3T will be compared. At 1.5T the current clinical protocol will be used to detect wall motion disturbances, abnormalities in perfusion and myocardial infarction. Within several weeks after the first MRI, a similar study will be performed at 3T, but with adjusted acquisition parameters compensating for higher field strength. Additionally, wall motion sequences will be performed after administration of the contrast agent gadofosveset.

Study burden and risks

MRI is a diagnostic tool with minimal burden for the patient. The use of contrast agents is associated with minimal risks. However, side effects of MR contrast agents are rare and, if they occur, they can generally be treated well. In previous trials with Gadofosveset, this agent has demonstrated to be useful and safe.

Contacts

Public
Academisch Ziekenhuis Maastricht

Peter Debijelaan 25
6229HX, Maastricht
NL
Scientific
Academisch Ziekenhuis Maastricht

Peter Debijelaan 25
6229HX, Maastricht
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

scheduled cardiac MRI for suspected ischemic heart disease
age: > 18 years en < 90 years
informed consent

Exclusion criteria

severe cardiac rhythm disturbances
hemodynamic unstable
contra-indications for contrast-enhanced MRI: absolute: pacemaker, pacemakerwires, implanted hearing aid, cerebral vascular clips. Relative contra-indications: neurostimulator, insulinpump, metal corpora aliena, claustrophobic patients, pregnancy, previous reaction on MR contrast agents
age: <18 years en > 90 years

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):	12-04-2007
Enrollment:	15
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Vasovist
Generic name:	gadofosveset trisodium
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	07-09-2006
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	12-10-2006
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	EUCTR2006-004583-32-NL
CCMO	NL14167.068.06