Cardiovascular Magnetic resonance imaging and Echocardiography in Rheumatoid Arthritis - Patterns of cardiovascular dysfunction in patients with rheumatoid arthritis

Published: 24-04-2012
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The main objective of the study is to document cardiovascular dysfunction found in rheumatoid arthritis and gout patients using cardiac imaging techniques echocardiography and cardiac MRI.

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

Summary

ID

NL-OMON39670

Source
ToetsingOnline

Brief title
CAMERA-trial

Condition

- Cardiac disorders, signs and symptoms NEC
- Joint disorders

Synonym
RA, rheumatics

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: via onderzoeksafdeling reumatologie en cardiologie MST

Intervention

Keyword: - cardiac magnetic resonance imaging, - cardiovascular disease, - chronic gout, - echocardiography, - rheumatoid arthritis

Outcome measures

Primary outcome

The main study parameters will be patterns of cardiovascular dysfunction in different groups of RA patients and gout using cardiac imaging techniques. To assess cardiovascular dysfunction, different variables will be scored including wall motion score, diastolic function, valvular abnormalities, left and right ventricular ejection fraction, left ventricular mass and presence of myocardial fibrosis.

With this pilot study we want to determine parameters that are useful for further follow-up studies in patient with RA and chronic gout in assessing cardiovascular risk with cardiac imaging techniques.

Secondary outcome

Not applicable.

Study description

Background summary

People with rheumatoid arthritis (RA) have a two- to threefold increased mortality risk compared to the general population. Death is mainly due to cardiovascular diseases, such as myocardial infarction, heart failure and

stroke. The pattern of cardiac disease manifestations seems to be different than in the general population. The way cardiovascular disease develops in these patients is greatly unknown. People with chronic gout also have an increased risk for cardiovascular mortality.

Study objective

The main objective of the study is to document cardiovascular dysfunction found in rheumatoid arthritis and gout patients using cardiac imaging techniques echocardiography and cardiac MRI.

Study design

Descriptive pilot study.

Study burden and risks

Patients will undergo cardiac magnetic resonance imaging (MRI) and echocardiography on two different days. During cardiac MRI, patients will receive intravenously contrast in order to be able to differentiate various types of cardiac pathology. There is a hypothetical risk of nephrogenic systemic fibrosis (NSF) associated with gadolium-based contrast used in MRI. NSF occurs exclusively in patients with kidney failure and as patients selected for this study will only be allowed to participate if renal function is within normal limits, it is highly unlikely to occur. The incidence of NSF due to the contrast used in this study is 0% according to the manufacturer. MRI-scanning can be unpleasant to people with claustrophobia. Patients with significant claustrophobia will be excluded from participation in this study. Furthermore, patients who are pregnant or have metal implants will be excluded.

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

rheumatoid arthritis patients with anti-CCP+ and RF+ laboratory results
patients with punctate proven gout

Exclusion criteria

male gender
previous cardiovascular disease
current smoking
history of kidney dysfunction, hypertension or diabetes mellitus
claustrophobia
body mass index > 30 kg/m2
pregnancy
metal impants

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2012
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	24-04-2012
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	04-04-2013
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	18-02-2014
Application type:	Amendment
Review commission:	METC Twente (Enschede)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 21327
Source: NTR

Title:

In other registers

Register	ID
CCMO	NL33959.044.10
OMON	NL-OMON21327