Reproducibility of qualitative, semi quantitative and quantitative DCE- MR Imaging in the knee.

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To evaluate the reproducibility of DCE-MRI measurement of the joints analyzed by color coded shape mapping, and by compartmental model analysis.

Ethical review	Approved WMO
Status	Pending
Health condition type	Autoimmune disorders
Study type	Observational invasive

Summary

ID

NL-OMON30767

Source
ToetsingOnline

Brief title
not applicable

Condition

- Autoimmune disorders
- Synovial and bursal disorders

Synonym
chronic inflammatory arthritis, rheumatoid arthritis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: arthritis, dynamic contrast enhanced MRI, reproducebility

Outcome measures

Primary outcome

DCE-MRI scans obtained at the two time points will be scored according to the omeract RAMRIS score by DCE-MR color coded shape mapping and by compartmental analysis (quantitative analysis) (appendix B).

Correlation between the two time points will be evaluated by the Spearman*s rank correlation coefficient. In addition the change in mean, within patient standard deviation, within patient coefficient of variation and the repeatability will be determined.

Differences between healthy individuals and arthritis patients will be evaluated to determine the basal level of enhancement

Secondary outcome

not applicable

Study description

Background summary

Magnetic Resonance Imaging (MRI) is a powerful technique that can be used to visualize and investigate the earliest changes in the joints of RA patients.
Synovitis is best viewed using pre-and post gadolinium (Gd DPTA) sequences, and can be quantified by static conventional MRI scans or by Dynamic Contrast Enhanced MRI scans (DCE-MRI).
DCE-MRI involves the dynamic sampling of the MR-signal during intravenous injection of the contrast agent (gd DPTA). Three methods are developed to evaluate tissue changes using the curves obtained with DCE-MRI. Each of these three methods has its drawbacks.
Because of the drawbacks, a new DCE-MR analysis and imaging method has been

developed, using a 3D pixel by pixel method to visualize shape curve distribution within the joint. In this study the reproducibility of the new method will be evaluated.

Study objective

To evaluate the reproducibility of DCE-MRI measurement of the joints analyzed by color coded shape mapping, and by compartmental model analysis.

Study design

Reproducibility of DCE-MRI will be evaluated by comparing MR analysis results obtained at 2 different time points from the joint of the same patient or healthy control. In addition parameters of disease activity, vital parameter, medical history and medication use will be recorded before each MRI.

Study burden and risks

Patients will undergo a contrast enhanced MRI of a knee joint twice. There are no known interactions of the contrast agent and any drugs. Patients can get an allergic reaction to the contrast agent but these reactions are rare. Participation takes 120 minutes in total.

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

RA-patients: artritis of a knee joint
Healthy volunteers: none

Exclusion criteria

RA-patients : claustrofobia, known allergy to gadolineum contrast agent
Healty volunteers: 1)history of joint disease 2)claustrofobia, known allergy to gadolineum contrast agent

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2007
Enrollment:	15
Type:	Anticipated

Ethics review

Approved WMO
Application type: First submission

Review commission: METC Amsterdam UMC

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	NL15726.018.07