Rheumatoid Arthritis Handscanner Observational Study. ‘Ontstekingsdetectie met behulp van licht’.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24015

Source
NTR

Brief title
RA-HOS

Health condition

Rheumatoid Arthritis

Sponsors and support

Primary sponsor: Sponsor: Akeso Medical Imaging
Perfomer: UMC Utrecht, Regionaal Reumacentrum Eindhoven
Source(s) of monetary or material Support: Akeso Medical Imaging

Intervention

Outcome measures

Primary outcome

The primary objective of this study is to create an algorithm for the Full Handscan Proto.

Secondary outcome

Secondary parameters are related to variables that may interfere with the optical measurements:

1. Effect of gadolinium i.v. on Full Hand Proto scanning after MRI testing;

2. Observed destruction and erosions in the joints of the hands and wrists, based on the most recent, or upcoming x-ray image as obtained during regular treatment;

3. Temperature;

4. Skin type (Caucasian, Mediterranean , Asian or Negroid);

5. Wounds;

6. Vasodilatative medication;

7. Vasoconstrictive diseases like Raynaud’s disease.

Study description

Background summary

Observational study to collect joint inflammation data in rheumatoid arthritis patients using a novel optical device and reference methods such as ultrasound and MRI. Data will be used to develop an data analysis algorithm for the optical device to visualize inflammation levels in hands and wrists of rheumatoid arthritis patients.

Study objective

N/A

Study design

Cross sectional first phase, monthly follow-up for patients with high initial disease activity during 6 months after cross sectional phase.

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

1. Diagnosed with rheumatoid arthritis for groups II-IV;

2. Age range between 18 and 90 years;

3. Ability to give informed consent.

Exclusion criteria

1. Diagnosed with an inflammatory joint disease for group I;

2. Significant visual deformations of the hand and fingers;

3. Recent surgery or operation in the last three months on wrist, hand or fingers;

4. Wheelchair bound patients;

5. Pregnancy or breastfeeding;

6. Light sensitivity, i.e. Erythropoietic protoporphyria;

7. Allergy to Gadolinium contrast for group II;

8. Metal objects in any organ or joint for group II;

9. Renal insufficiency defined as MDRD < 30ml/min/1.73m2 for group II.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-01-2012
Enrollment:	70
Type:	Anticipated

Ethics review

Positive opinion

Date:	11-01-2012
Application type:	First submission

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
NTR-new	NL3081
NTR-old	NTR3229
Other	METC UMCU / CCMO : 10-395/E / NL34559.041.10.v2
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A