Rheumatoid Arthritis Handscanner Observational Study

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The present clinical study is part of the development and evaluation of the Full Hand Proto (FHP) to measure disease activity in the joints of hands and wrists of rheumatoid arthritis patiens based on optical attenuation measurements.

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

Summary

ID

NL-OMON37927

Source
ToetsingOnline

Brief title
RA-HOS

Condition

- Autoimmune disorders
- Joint disorders

Synonym
Arthritis, Rheumatoid Arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Akeso Medical Imaging BV
Source(s) of monetary or material Support: Akeso Medical Imaging BV

Intervention

Keyword: disease activity, Full Hand Pro, Optical transmission spectroscopy, rheumatoid arthritis

Outcome measures

Primary outcome

- To collect data to develop a diagnostic model (algorithm) based on the optical transmission measurements performed by the FHP that can predict the joint inflammation level as assessed by currently accepted methods, such as DAS28, ultrasound, MRI, blood tests and questionnaires.

- To evaluate in a cross-sectional study (part I) the level of agreement between predictions of disease activity from optical spectral transmission measurements (algorithm) and conventional disease activity measurements in rheumatoid arthritis patients, i.e. ultrasound, magnetic resonance imaging (MRI), physical examination by a physician (number of swollen and tender joints), blood tests and questionnaires.

- To evaluate in a longitudinal study (part II) the correlation between (changes in) optical spectral transmission measurements and DAS28 measurements in patients with severe RA in the cross-sectional part during 6 months.

Secondary outcome

To assess the influence of variables on optical transmission measurements:

• Erosions and destruction in joints of the hands and wrists

• skin temperature and type

• wounds

• vasodilatative medication

• vasoconstrictive diseases like Raynauds disease

Study description

Background summary

Treatment-decisions in patients with rheumatoid arthritis are usually based on DAS-28, a composite measure consisting of measurements from physical examination (swollen and tender joint counts), patient reported outcomes and laboratory results. It is well known that there may be disease activity despite of remission measured by DAS-28, and further that DAS-28 is influenced by factors unrelated to activity of rheumatoid arthritis. An increasing need is felt for objective measuments of disease activity. Currently, more and more ultrasound and MRI are applied for this goal. Both have several drawbacks, for example ultrasound is operator-dependent and MRI is expensive. Optical transmission spectroscopy offers several advantages over these existing modalities; it is operator-independent, its costs are relatively low and it is harmless at relevant wavelengths and intensities. A new device, the Full Hand Proto (FHP) has been realized by Philips Research. This device can assess all joints in hands and wrists. Preliminary results in a recent pilot study showed good correlation between clinical assement of disease activity.

Study objective

The present clinical study is part of the development and evaluation of the Full Hand Proto (FHP) to measure disease activity in the joints of hands and wrists of rheumatoid arthritis patiens based on optical attenuation measurements.

Study design

Part I is a cross sectional, nonrandomized observational study in patients with rheumatoid arthritis (RA). Part II is a follow-up longitudinal observational study in patients selected from study part one with severe RA. We will evaluate in a cross-sectional study (part I) the level of agreement between predictions of disease activity from optical spectral transmission measurements and conventional disease activity measurements in rheumatoid arthritis patients, i.e. ultrasound, magnetic resonance imaging (MRI), physical examination by a physician (number of swollen and tender joints), blood tests and questionnaires. We will evaluate in a longitudinal study (part II) the correlation between (changes in) optical spectral transmission measurements and DAS28 measurements in patients with severe RA in the cross-sectional part during 6 months. All subjects will receive treatment as usual throughout the

study.

Study burden and risks

Patients will have to pay an extra visit to the hospital. The measurements will take 3 hours (4 in case of MRI). The risks are small, in the subgroup in which MRI will be performed there is small risk of allergy to the gadolinium contrasts. In the subgroup with high disease activity will be asked at their regular doctors appointment to undergo optical transmission measurements and fill out questionaires. This will take an estimated 20 minutes per month during 6 months. The study may benefit future patients with reumatoid arthritis, because with the Hand Scan Pro hopefully a better estimate of disease activity may be obtained.

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

1. diagnosis of Rheumatoid Arthritis (or artralgia for control group)
2. No significant visual deformations of the hand and fingers
3. Patients between the age of 18 and 90 years
4. Ability to give informed consent

Exclusion criteria

- Recent surgery or operation, in the last three months, on the wrist, hand or fingers
- Allergy to gadolinium contrast (only for subgroup)
- Metal objects in any organ or joint (only for subgroup)
- Claustrofobia (only for subgroup)
- Estimated creatinine clearance by MDRD < 30 ml/min (only for subgroup)
- Patients in a wheelchair
- Pregnancy or breastfeeding
- Light sensitivity, i.e. Erythropoietic protoporphyria

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):	09-01-2012
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO Date:	21-12-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	25-04-2012
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	NL34559.041.10