Rheumatoid Arthritis Disease Activity Monitor

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

Summary

ID

NL-OMON33746

Source
ToetsingOnline

Brief title
RADAM RRC

Condition

- Joint disorders

Synonym
RA, Rheumatoid Arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Philips
Source(s) of monetary or material Support: middelen door industrie;personeel uit eigen budget

Intervention

Keyword: Monitoring, RA, RADAM, Rheumatoid Arthritis

Outcome measures

Primary outcome

Primary endpoint is a successful measurement of optical attenuation of a joint

and the part of the finger next to the joint before, during and after two

consecutive restrictions of venous blood flow by means of a pressure cuff.

Secondary outcome

Secondary endpoints are unsuccessful measurements related to early termination

of the measurement related to patient discomfort or safety and equipment or

software failure.

Study description

Background summary

Rheumatoid Arthritis (RA) is an autoimmune disease. There are four stages of the disease:
1. Synovial inflammation
2. Swelling of synovium
3. Pannus formation
4. Advanced bone and cartilage destruction

Currently, there is no cure for RA, making the disease a chronic condition. RA is more prevalent in elderly and women. With medication it is possible to delay the onset of complications. Over the last decade, the treatment of RA has changed. Where treatment was palliative until pain medication was ineffective, the treatment is now more aggressive with early administration of disease modifying drugs (DMARDs).
The treatment for RA is staged. First, the patient receives generic, low-cost drugs. If this treatment becomes ineffective, the treatment is adjusted with different and usually more advanced drugs. Biologics are a category drugs that are considered most advanced and most expensive.
For effective treatment, there are two unmet needs.
• A tool to aid early diagnosis, as this allows early treatment and delay of

complications and physical restrictions for patients.
• A safe, simple and cheap tool to monitor disease progress to allow traceable, operator-independent informed decisions on treatment adjustments.
Non-invasive optical methods offer several advantages over existing modalities. Optical contrast can be related to physiological parameters in the body, such as blood concentration and oxygenation. At relevant wavelengths and intensities, optical radiation is completely harmless. The cost of optical methods is low compared to other modalities. An important application, where optical methods can help diagnosis and treatment is detection of inflammation of joints in patients suffering from rheumatoid arthritis (RA). Due to the highly scattering nature of tissue, non-invasive optical methods for medical imaging are limited to the extremities of the human body. For application in joint diseases, this is acceptable, because imaging of hands can provide sufficient clinical information.

Study objective

Primary objectives
This is a retrospective, nonrandomized controlled observational study, conducted in a single center to evaluate the potential of optical attenuation measurements to establish disease activity for rheumatoid arthritis patients.
Secondary objectives
Establish parameters from transient optical transmission measurements of the joint that relate to clinical evaluation results of individual joints
Evaluate relation between disease activity (DAS-28 score) and the optical attenuation spectra of the fingers of a patient.

Study design

This is a cross sectional, nonrandomized controlled observational study, conducted in a single center to evaluate the potential of optical attenuation measurements to establish disease activity for rheumatoid arthritis patients.

Study burden and risks

The subject will sit for 5 minutes with a hand placed on a sphere. One finger will be placed between two sets of two fibers. During the 5 minutes of the measurement a pressure cuff will be inflated twice to 50mmHg for the duration of 1 minute.
Based on the risk management report, the risks are classified as negligible.

Contacts

Public

Philips

High Tech Campus 5
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Nederland
Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Diagnosed with Rheumatoid Arthritis
Inflamed PIP joint of at least one index finger (moderate or severe)
Disease activity of specific joints known (swelling, tenderness)
No significant deformations of the hand or fingers
More than 18 years old

Exclusion criteria

Recent surgery or operation, in the last three months, on the arm or fingers that will be tested with the RADAM RRC.
Inability to give informed consent

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-02-2009
Enrollment:	75
Type:	Actual

Ethics review

Approved WMO Date:	26-01-2009
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	10-03-2009
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL25682.015.08