Optisch spectraal transmissie voor therapie monitoring en correlatie met arteriële vaatstijfheid bij patiënten met reumatoïde artritis die gaan starten met TNF remmende therapie

No registrations found.

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

Summary

ID

NL-OMON20387

Source
NTR

Brief title
Handscan PWV

Health condition

Rheumatoid arthritis,
Cardiovascular disease

Sponsors and support

Primary sponsor: Reade Center for Rehabilitation and Rheumatology
Source(s) of monetary or material Support: Reade Center for Rehabilitation and Rheumatology

Intervention

Outcome measures

Primary outcome

The main study parameters are the results from the handscan measurement, arterial stiffness as measured with pulse wave velocity and augmentation index, DAS28 and the ultrasound assessment of the hand joints at all time points.

Secondary outcome

N/A

Study description

Background summary

In the last decade, treatment advances in rheumatoid arthritis (RA) have resulted in a tremendous improvement in therapeutic outcomes. One of these advances is treat-to-target therapy. However, a valid detection instrument for disease activity is still necessary. Currently a composite measure called Disease Activity Score (DAS28) is used for this. However, a new imaging device called handscan might be an appropriate disease activity detection instrument as well. Measurements with the handscan are fast and probably less investigator-dependent. The handscan uses hemodynamics of the smaller vessels to measure inflammation in the hand joints and therefore a correlation between the handscan measurement and arterial stiffness, as assessed with pulse wave velocity, might be present.

The objectives of this study are to investigate the correlation of the handscan measurement with DAS28 and ultrasound measurement of the hands and to investigate the responsiveness to therapy of the handscan device. Also the correlation between the handscan and arterial stiffness will be investigated.

Study objective

N/A

Study design

Baseline, 1 month and 4 months.

Intervention

N/A

Contacts

Public

Scientific

Eligibility criteria

Inclusion criteria

- 18 years or older

- Active rheumatoid arthritis in hands or wrists, defined as ≥ 2 swollen hand joints (IP, PIPs and/or MCPs) or ≥ 1 swollen wrist joints

- Starting with TNF-inhibiting therapy (first- or second line)

Exclusion criteria

- Surgery in wrist or hand in the preceding 3 months

- Other active concomitant musculoskeletal disease

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	08-01-2018
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion
Date: 30-08-2018

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48787
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7257
NTR-old	NTR7479
CCMO	NL64183.048.17
OMON	NL-OMON48787

Study results