Optical spectral transmission imaging for treatment monitoring and correlation with arterial stiffness in patients with rheumatoid artritis starting with TNF inhibiting therapy

Published: 16-01-2018
Last updated: 15-05-2024

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…

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

Summary

ID

NL-OMON48787

Source
ToetsingOnline

Brief title
Handscan PWV

Condition

- Joint disorders

Synonym
inflammatory arthritis, rheumatoid arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Reade
Source(s) of monetary or material Support: Reade

Intervention

Keyword: arterial stiffness, handscan, optical spectral transmission, therapy monitoring

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

(baseline, 1 month and 4 months).

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.

Study objective

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 design

Multi-center longitudinal prospective observational cohort study

Study burden and risks

Due to the observational nature of this study risks are minimal. Handscan measurement and ultrasonography is non-invasive and safe. Only sampling to determine ESR and CRP might cause some minor discomfort. From a larger perspective, the findings from this study will hopefully provide information that might contribute to better care for rheumatoid arthritis patients.

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

Rheumatoid arthritis group
- 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;Hypertension group
- 18 years or older
- Patients with hypertension, defined as systolic blood pressure >140 mmHg and/or diastolic blood pressure >90 mmHg or currently on antihypertensive treatment
- No rheumatoid arthritis;Healthy controls group
- 18 years or older
- No hypertension, defined as systolic blood pressure *140 mmHg, diastolic bloodpressure * 90 mmHg and no antihypertensive treatment
- No rheumatoid arthritis

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-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2018

Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	16-01-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-10-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-03-2019
Application type:	Amendment
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

ID: 20387
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL64183.048.17
OMON	NL-OMON20387

Study results

Date completed:	12-07-2019
Actual enrolment:	62