Handscan Registry Leeuwarden

No registrations found.

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

Summary

ID

NL-OMON21538

Source
NTR

Health condition

Rheumatoid arthritis

Sponsors and support

Primary sponsor: Stichting De Friesland
Source(s) of monetary or material Support: Stichting Innovatie en Onderzoek Reumatologie

Intervention

Outcome measures

Primary outcome

Asscociation of optical score of the Handscan with DAS 28 and changes in medication

Secondary outcome

DAS 44
Assessment of the current complaints of different domains.
HAQ
MHOQ: Michigan hand outcome questionnaire
The extent of erosions at begin and end of the study (modified Sharp-van der Heijde score).

All RA-related admissions and adverse events.

Study description

Background summary

Prospective blinded observational study (registry) investigating the additive value of the diffuse optical imaging (the Handscan) to daily clinical practice in patients with rheumatoid arthritis. We will perform a blinded Handscan in a large group of RA patients during two years. After two years we will investigate the association of Handscan and different disease activity scores and the predictive value for help in clinical decision making such as changes in medication.

Study objective

The Handscan is supposed to be more accurate than the current widely used DAS 28, it might be able to measure subclinical disease activity.
We want to investigate in which clinical situation, the handscan can be an aide in decision making or can be used as a subtitute for health care professionals.

Study design

Follow up of patients with RA for a period of two years. A handscan will be made every regular visit before going to the health professional.

Intervention

None

Contacts

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Eligibility criteria

Inclusion criteria

RA diagnosis according to ACR/EULAR criteria with at least two years duration.
Age> 18 years.
Able to place the hands flat on the scan plate.
Voluntary contribution in the study.
Able to give an informed consent.

Exclusion criteria

Hypersensitivity to light.
Hand surgery in the last month before inclusion.
Patient who can’t full the questionnaire with out help

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-11-2017
Enrollment:	600
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	08-02-2019
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	NL7500
Other	METC MCL/ CCMO : nWMO257

Study results