Assessment of Generalized Pain Hypersensitivity in Rheumatoid Arthritis

No registrations found.

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

Summary

ID

NL-OMON21279

Source
NTR

Brief title
TBA

Health condition

Rheumatoid Arthritis / Fibromyalgia

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: NA

Intervention

Outcome measures

Primary outcome

• Evaluation of the 2-week test-retest reliability of the Generalized Pain Questionnaire (GPQ);
• Exploration of the effect of pain sensitivity measurements (PPT, EPT and NDT) and questionnaires (CSI, GPQ, SF-36, and PCS) in Rheumatoid Arthritis patients and its relation to the painful-to-swollen joint count ratio;

Secondary outcome

• Evaluation of the criterion validity of the GPQ against the pain sensitivity measurements (PPT, EPT and NDT).

Study description

Background summary

Rationale: Over the last two decades, there have been many improvements in th0e pharmacological treatment of rheumatoid arthritis (RA). However, pain in RA often remains problematic, as the mechanism of persistent pain may originate from central pain regulatory mechanisms, rather than persistent peripheral stimuli of nociceptors. As such, instruments able to identify the presence and severity of generalized pain hypersensitivity could be useful in clinical management of RA. For that reason, in this study we want to evaluate the effect of RA on questionnaires and pain sensitivity measurements that are aimed at evaluating generalized pain hypersensitivity in humans.
Objective: Examination of the test-retest reliability (two weeks) and measurement errors of the recently developed and validated self-report generalized pain questionnaire (GPQ). Further, the usefulness of three pain sensitivity measurements (PPT, EPT and NDT) in RA will be evaluated. As a secondary objective, the evaluation of the criterion validity of the GPQ against the pain sensitivity measurements (PPT, EPT and NDT) will be explored.
Study design: Mono-center, cross-sectional study with a two-week follow-up questionnaire.
Study population: 61 patients from the rheumatology department of the Medisch Spectrum Twente (MST) Hospital. 50% of the included participants are required to show a discrepancy of ≥7 painful to swollen joints; which is a score present in about 10-20% of the patients at the MST rheumatology department. The other participants will have no discrepancy between the painful and swollen joints, and will be age-matched to the participants in the other group.
Main study parameters/endpoints: Several (pain) questionnaires such as the CSI, SF-36, GPQ, PCS, NRS and Patient Global Assessment of Change in Disease Activity. Furthermore, three types of pain sensitivity measurements will be performed: PPT, EPT and NDT.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients are expected to visit the MST once for a session wherein all questionnaires are filled in and pain sensitivity measurements will be performed. This session will take approximately 50 minutes. Two weeks after this session, participants are asked to fill in the GPQ and Patient Global Assessment of Change in Disease Activity questions and send these back to the MST. All participants will be compensated for the spent time. The participants will obtain no direct personal benefit. The risks involved in this study are considered to be minimal to none.

Study objective

Patients with a discrepancy between between painful-to-swollen joints have a lower score on pain sensitivity measurements (PPT, EPT and NDT) and a higher score on questionnaires (CSI,

GPQ, SFD-36 and PCS).

Study design

Measurement session at MST, two weeks later a follow-up questionnaire needs to be filled in and send to MST from home.

Contacts

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Eligibility criteria

Inclusion criteria

(1) A signed, written informed consent, (2) Clinical diagnosis of Rheumatoid Arthritis, (3) Patient at the Rheumatology Department of the MST Hospital

Exclusion criteria

(1) Patient's refusal during the study, (2) Skin problems at one of the sites of the pain sensitivity measurements, (3) Language problems, (4) Diabetes, (5) Small fiber neuropathy, (6) Implanted stimulation device, (7) Pregnancy, (8) Unable to undergo pain sensitivity measurements, (9), Age >70 years old

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-08-2020
Enrollment:	61
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	06-07-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 52423
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8760
CCMO	NL73282.100.20
OMON	NL-OMON52423

Study results