Enabling rapid differentiation of rheumatic musculoskeletal disorders in patients with rheumatic musculoskeletal complaints

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Objective: I) Test the ability of JPAST (Joint Pain Assessment Scoring Tool) to discriminate patients with and without rheumatic musculoskeletal diseases (RMDs) in patients referred to the rheumatology outpatient clinic. II) Compare the JPAST*s...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON55318

Source
ToetsingOnline

Brief title
identify rheumatic diseases

Condition

- Other condition
- Autoimmune disorders
- Joint disorders

Synonym
rheumatic musculoskeletal complaints, rheumatic musculoskeletal disorders

Health condition

spieraandoeningen

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum
Source(s) of monetary or material Support: aanvraag loopt,aanvraag loopt

Intervention

Keyword: efficiency, genetics, rheumatology, serology

Outcome measures

Primary outcome

Intervention : questionnaires, HandScan and blood withdrawal of 15ml

Main study endpoints:

• RMD diagnosis

• Termination of follow-up at Rheumatology outpatient clinic

Secondary outcome

Additional parameters:

• JPAST score based on:

- Serology panel

- Genetics panel

- Web based questionnaires on clinical symptoms called Rheumatic?

• Health record information

- Medication usage before and after symptoms onset

- New medical diagnoses after first visit to the rheumatology outpatient clinic

- Co-morbidities

- Medical history

- GP Referral letters

• Genome- wide typing (~750.000 single nucleotide polymorphisms)

• MRI HandScan - scanning for inflammatory arthritis in the hands.

• Additional questionnaires:

- Life-style questionnaire: de Vita-16© 6,7

- Physical activity questionnaire SQUASH7-9

- ZDC Rheumatology questionnaire

Study description

Background summary

Rationale:
The continuous increase in national healthcare expenses has led to the agreement between health care providers and the Dutch government to diminish this growth (hoofdlijnenakkoord).1 This agreement necessitates health care providers to improve care efficiency for instance to with regards to correct patient referrals from general practitioners (GPs) to the medical specialist.

Rheumatic and Musculoskeletal Diseases (RMDs) affect 5% of the population, while 35% of the population experiences Rheumatic and Musculoskeletal Complaints (RMCs).2 Timely disease identification is essential to prevent harm for patients and society. Similarly important is the early identification of patients with RMCs without RMDs to prevent unnecessary health care expenses. Ideally, we would equip GPs with our (scientific) knowledge about RMDs to allow this differentiation before referring patients to the rheumatology outpatient clinic.

Currently, patient triage is done using the GPs referral letter and if possible a questionnaires for the patients. Some centers are experimenting with the hands scan to identify early synovitis. New tools are being developed. A promising tool is JPAST (Joint Pain Assessment Scoring Tool) is a diagnostic tool developed in Sweden and tested in Germany and England. The tool combines self-reported clinical information, serology and genetics.3 The strength of this tool is that it combines all our current knowledge on rheumatic disease and aims to guide patients and GPs about the likeliness of a patient having a RMD. Currently, the tool is not yet validated in the Netherlands. Our study will validate JPAST in the Dutch population, compare the tool with current triage systems and search for factors to improve the differentiation between patients with RMDs from patients with only RMCs. We aim for the most efficient

screening method with a high accuracy.

The final tool this tool could prevent unnecessary referrals to the rheumatology clinic and prevent delay in referrals of patients with (serious) RMDs.

Study objective

Objective:
I) Test the ability of JPAST (Joint Pain Assessment Scoring Tool) to discriminate patients with and without rheumatic musculoskeletal diseases (RMDs) in patients referred to the rheumatology outpatient clinic.
II) Compare the JPAST*s performance with current ongoing triage systems in the Netherlands (HandScan4,5 and questionnaire)
III) Improve JPAST by identifying novel discriminatory factors for RMDs within patients with RMCs through examination of long-term clinical information, genetics, vitality and life-style.

Study design

Longitudinal observational prospective (five years) study including retrospectively (ten years) obtained data, with two year recruitment period.

Study burden and risks

We ask participants to fill out the questionnaires, give 15ml of blood, scan their hands and allow access to their medical records for the past ten years and upcoming five years. Since our study requires little effort from participants, the risk and burden of all these interventions is very low. The amount of collected information is highly relevant to improve the research to RMDs. Our request to access clinical information before and after patients* first visit to our clinic is relevant since many RMDs take years to develop and critical events likely occurred years before their first visit. Likewise, it might take years after a patient*s first visit before their disease has fully developed.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Patients newly referred to the rheumatology outpatient clinic.
- >17yrs at time of referral
- proficiency in Dutch

Exclusion criteria

< 18 years of age
incompetent to act for oneself

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2020
Enrollment:	2000
Type:	Anticipated

Medical products/devices used

Generic name:	HandScan
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	07-12-2020
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	27-06-2022
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	08-01-2024
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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	NL74767.099.20