Effect of ageing on interpretation of disease activity measures and on cognition, physical activity and performance in patients with rheumatic disorders.

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In the STudying Ageing in Rheumatic diseases (STAR) project, our main goal is to: study the ageing process in patients with and without RA and specifically assess the impact of ageing on (1) the interpretation of commonly used measures of disease...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Autoimmune disorders
Study type	Observational invasive

Summary

ID

NL-OMON52497

Source
ToetsingOnline

Brief title
STudying Ageing in Rheumatic diseases (STAR)

Condition

- Autoimmune disorders
- Synovial and bursal disorders

Synonym
musculoskeletal disorders, Rheumatic diseases

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Farmacie;Pfizer.,Pfizer

Intervention

Keyword: Ageing, Disease activity, Outcome, Rheumatoid arthritis

Outcome measures

Primary outcome

Primary objective: to investigate how measures of disease activity and measures for cognition, physical activity and performance behave in ageing population controls and RA patients. If an differential effect of age on outcome over time is apparent, the presence of an inclination point will be assessed.

Secondary outcome

Secondary objective: in case of differences between ageing RA patients and population controls, we will also investigate what additional factors might explain these differences.

Study description

Background summary

The rate of the demographic ageing process in the Netherlands will double in the years to come. The Dutch population is anticipated to grow to 17.8 million around 2040, of which 4.6 (26%) million people will be 65 years of age or older. As the *baby-boomers* age, the number of patients with inflammatory arthritis, including those with rheumatoid arthritis (RA), will also increase.

The evolving demographical transition of the *RA population* makes it necessary to critically review ageing and comorbidity in RA and the possible impact of these factors on (1) disease-specific instruments used to make treatment decisions and (2) cognitive, physical activity and performance.

Currently, it is unclear whether disease activity measures commonly used in treat-to-target strategies are directly transferrable to elderly RA patients. Only limited evidence for the effect of ageing on general and disease-specific RA instruments exists: ageing by itself may have a negative impact on both the pain Visual Analogue Scale (VAS) and global assessment VAS. Sokka et al. concluded that only 15% of the general population > 50 years old meet all four American College of Rheumatology (ACR) remission criteria.

More evidence on how disease instruments behave in elderly individuals, is therefore urgently needed. To know whether a difference in performance of i.e. the DAS28 is due an age-effect or due to a change in physiological disease activity (patient adaptation), population data are needed. In addition, it is important to gain insight in outcomes that seem relevant but are currently not explicitly accounted for in the care for elderly RA patients, such as a decline in cognition, physical activity and performance. These questions will be answered in the current research proposal.

Study objective

In the STudying Ageing in Rheumatic diseases (STAR) project, our main goal is to: study the ageing process in patients with and without RA and specifically assess the impact of ageing on (1) the interpretation of commonly used measures of disease activity and (2) cognition, physical activity and performance. Baseline data from the STAR cohort (population controls and RA patients), which we aim to set up in the context of this proposal, will be used.

Study design

Study design: observational cross-sectional matched case - control study.

In total, 420 RA patients and 420 population controls between 55 and 85 years of age, stratified according to age at five year intervals, will be included. These subjects, between 55 and 85 years of age, will fill out (RMD-specific) questionnaires and undergo cognitive testing.

Part of de participants (n = 240) will also undergo blood analyses, a physical examination and physical tests.
By comparing the outcomes of RA patients with population controls, we can study the effect of ageing on the outcome measure.

Study burden and risks

All participants need to complete generic and RA-specific questionnaires. Patients > 80 years who are physically unable to complete the whole study procedure (i.e. geriatric patients who are considered frail by the rheumatologist / researcher and/or patient itself), are allowed to undergo only

part of the study measurements / questionnaires. For the 240 participants who also visit the research center for additional measurements, this extra visit will take about 1 hour. Completing the questionnaires at home (on paper or online), including a telephone interview, will take 2-3 hours.
All 240 patients and controls will be seen in one study visit by 1-2 trained research assistant(s), using standardized protocols. Participants will undergo a physical examination, physical and laboratory (three blood samples; one venepuncture) testing.
The physical examination, cognitive testing (via telephone interview) and laboratory tests may reveal prevalent disease, such as hypertension or cognitive deficits. If any of the participants do not wish to undergo cognitive testing, he or she will continue according to protocol without having fulfilled this item and without further consequences. The participant will specifically be given the opportunity to opt out for cognitive testing. If a participant is suspected of cognitive dysfunction (TICS score < 34) we will inform the treating rheumatologist in case of a patient or general practitioner in case of a control. The rheumatologist or general practitioner can bring this participant into care for further analyses via the outpatient clinic for cognitive (dys)function (*geheugenpoli*), after consulting the participant.
With regard to participation risks and benefits: all subject will get after participation a (telephone) meeting with the researcher to discuss the findings. Abnormal laboratory values or abnormalities during physical examination of potential clinical importance will always be discussed with the patient and the rheumatologist / general practitioner. Awareness of normally unknown pathology may affect a person*s perception of his/her own health condition negatively. On the other hand, early detection of for instance hypertension or cognitive dysfunction has potentially favourable effects on disease progression and may enable early intervention.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Inclusion criteria

Inclusion criteria, RA population
- Age between 55 - 85 years at baseline.
- Diagnosis of RA by treating rheumatologist.
- Patients > 80 years who are physically unable to complete the whole study procedure (i.e. geriatric patients who are considered frail by the rheumatologist and/or patient itself), are allowed to undergo only part of the study measurements. The rheumatologist who invites a patient > 80 years explains this option to the patient; the patient is then allowed to choose which measurement protocol suits him/her best.

Inclusion criteria, control population
- Age between 55 - 85 years at baseline.
- No diagnosis of RA, or other inflammatory RMD (osteoarthritis allowed).
- Controls > 80 years who are physically unable to complete the whole study procedure (i.e. geriatric controls who are considered frail), are allowed to undergo only part of the study measurements. The research assistant who contacts the control after a control indicated his/her interest in the study, explains this option to the control; the control is then allowed to choose which measurement protocol suits him/her best.

Exclusion criteria

Exclusiecriteria:
- Have severe comorbidity and the treating rheumatologist or research team decides they should not be included in the study because of health reasons.
- Do not understand the Dutch language and/or are not able to understand the study information.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-12-2022
Enrollment:	840
Type:	Actual

Ethics review

Approved WMO Date:	01-06-2021
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	01-06-2022
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	17-01-2025
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL71972.068.19