

The effect of exercise on cardiorespiratory fitness in patients with Rheumatoid Arthritis and Cardiovascular risks

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON46779

Source

ToetsingOnline

Brief title

Exercise in patients with Rheumatoid Arthritis and Cardiovascular risks

Condition

- Joint disorders

Synonym

Arthritis and cardiovascular risk factors, Rheumatoid Arthritis and Cardiovascular risks

Research involving

Human

Sponsors and support

Primary sponsor: Amsterdam Rehabilitation Research Center Reade

Source(s) of monetary or material Support: Interne betaling Reade

Intervention

Keyword: Cardiorespiratory fitness, Cardiovascular disease, Exercise therapy, Inflammation, Rheumatoid Arthritis

Outcome measures

Primary outcome

Primary outcome of the study is cardiorespiratory fitness assessed with a graded exercise tolerance test on an exercise bike (Lode, the Netherlands).

Secondary outcome

Secondary outcomes are functional performance, CV risk factors and disease activity.

Study description

Background summary

Rheumatoid arthritis (RA) is associated with increased overall mortality compared to the general population, with cardiovascular diseases (CVD) as one of the main causes. The optimization of management of CV risk in RA patients is an important aim in the treatment. Active counseling is indispensable, including also attention to exercise, particularly in RA patients with a high CV risk, defined as a 10-year CV risk of 20% or higher. Physical exercise for these patients is necessary and challenging since professionals should take multiple factors into account, such as comorbid conditions related to CV risk (e.g. hypertension, diabetes mellitus and obesity). However, the effects of exercise therapy on CV risk in RA patients are unknown and the required intensity is also unknown.

Study objective

The first aim of the present study is to develop a tailor-made exercise therapy program for these complex patients. The second aim is to evaluate the effect of exercise therapy in a pilot study on cardiorespiratory fitness and several secondary outcomes (i.e. safety, functional performance, CV risk factors, and

disease activity).

Study design

An experimental pre-posttest within-study design.

Intervention

The exercise therapy program will include exercises that are primarily aimed at improving cardiorespiratory fitness and functional performance in RA patients. Frequency, intensity, time, type and progression of the exercises will be performed according to the ACSM guideline (Durnstine 2009).

Study burden and risks

The workload and risks for patients are

1. The number of blood tests: 2x (in case of recent test, no repetition of blood draw)
2. The number of visits to the physician / researcher: 1x at rheumatologist and rehabilitation physician, then 3 measurements in the clinimetric laboratory and 12 weeks of training at a physiotherapist.
3. Physical examination: Standard protocol at physician and 2-3 x testing of cardiorespiratory fitness
4. The number and type of questionnaires and / or diaries: 4x general questionnaires are taken and RA specific questionnaires.
5. The physical discomfort: during cardiorespiratory exercise tests fatigue occurs.
6. Possible adverse side effects of treatment. Dosage of exercises is related to exercise tests, which means that the risk of overload is low.

In the light of the workload and / or risks, the measurements and treatment, the conduct of the investigation is justified.

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

- Diagnosis of RA fulfilling the ACR/EULAR classification criteria
- High 10-year CV risk (*20%) calculated with the Dutch SCORE table
- Age >20 and <80 years

Exclusion criteria

- Comorbidity which severely affects functional ability (CIRS*2),
- K&L grading of *3 for hip and/or knee OA
- Contra-indication for exercises according to the ACSM guideline (Durnstine 2009) i.e., progressive increase in heart failure symptoms, myocardial infarction less than 3 months before the start of the training program, severe ischemia of the cardiac muscle upon exertion, respiratory frequency of more than 30 breaths per minute and heart rate at rest >110 bpm.
- Insufficient control of the Dutch language and/or cognitive problems.

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 27-08-2018

Enrollment: 41

Type: Actual

Ethics review

Approved WMO

Date: 29-11-2017

Application type: First submission

Review commission: METC Amsterdam UMC

Approved WMO

Date: 28-10-2018

Application type: Amendment

Review commission: METC Amsterdam UMC

Approved WMO

Date: 26-11-2018

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

No registrations found.

In other registers

Register	ID
Other	In aanvraag
CCMO	NL63018.048.17