Conditioning and Health Training in Rheumatoid Arthritis

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20702

Source
NTR

Brief title
EXPECT HEALTH

Health condition

Pharmacological conditioning with or without an online guided health training in patients with recent-onset rheumatoid arthritis.
Farmacologisch conditioneren met of zonder een online begeleide gezondheidstraining in patiënten met nieuw-gediagnosticeerde reumatoïde artritis.

Sponsors and support

Primary sponsor: Leiden University
Source(s) of monetary or material Support: European Research Council Consolidator Grant

Intervention

Outcome measures

Primary outcome

The main study endpoint is the difference in the percentage of patients who achieve a drug-

free
clinical remission (Disease Activity Score DAS < 1.6) between the combined intervention groups (Conditioning group and Conditioning with Health Training group) and the Control group following the tapering period (12 months after the start the of the treatment).

Secondary outcome

Secondary study parameters are percentage of clinical remission at 8,12, and 16 months after the start of the treatment, disease activity, cytokine parameters, and other psychological outcome measures assessed at each measuring point.

Study description

Background summary

The main aim of this study is to evaluate a conditioning procedure with or without the combination of an online guided health training, aimed at optimizing pharmacological treatment effects. Patients, researchers and clinicians will be blind as to when a high dose is given and when a low dose is given. Patients in the combined experimental group will additionally receive an online guided health training, based on cognitive behavioral therapy principles. The intervention groups will be compared to a standard-treatment control group. Effects on percentage of drug-free clinical remission and other psychophysiological and psychological outcome measures will be examined at 8, 12, and 16 months after the start of treatment.

Study objective

The aim of the study is to enhance pharmacotherapeutic effects in patients with recent-onset rheumatoid arthritis by means of pharmacological conditioning with or without an online guided health training. It is expected that the interventions will lead to enhanced pharmacotherapeutic effects, as expressed in a larger percentage of patients in drug-free clinical remission (primary hypothesis), as compared to standard treatment.

Study design

The study is divided into four periods of four months (16 months in total), with measuring points at the beginning and end of each four-month period, thus comprising 5 assessment points in total (at baseline and 4, 8, 12, and 16 months after start of treatment).

Intervention

current pharmacological treatment recommendations. The study is divided into four periods of four months, with all groups receiving the same cumulative amount of active medication

during each period:

1. Month 1-4: After initial screening, patients who are eligible for stable standard pharmacological treatment will start on MTX and prednisone.

2. Month 5-8: Only patients who completed the baseline period without protocol violations and achieved clinical remission (DAS < 1.6) will continue to the second phase of the study and will be randomized to one of three groups. The different groups will follow different treatment schedules:

a. Control group: standardized treatment dosage (240 mg MTX in total) without health training.

b. Conditioning group: variable treatment dosage of MTX (240 mg MTX in total), without health training.

c. Conditioning with Health Training group: same pharmacological schedule as the Conditioning group (240 mg MTX in total) combined with a health training. Patients will be blind to the pharmacological treatment schedule.

3. Month 9-12: During the third period, MTX will be tapered and discontinued if patients are still in clinical remission (DAS<1.6), with dosages either decreasing linearly (Control group) or variably (Conditioning group and Conditioning with Health Training group), with the same total dosage in all groups.

4. Month 16: End-of-study visit.

Patients will visit the treating hospital for five appointments over a period of 16 months (at screening and after each period, T1-T5, see Figure 1), coinciding with patients' regular appointment as much as possible.

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Eligibility criteria

Inclusion criteria

1. Adult (minimum age of 18 years)

2. Recent-onset rheumatoid arthritis according to the revised American College of Rheumatology (ACR) criteria

3. Fluent in Dutch

4. Able to give informed consent

5. Clinical remission at month 5 after completing the protocolized pharmacological treatment.

Exclusion criteria

1. Previous therapy with DMARDs or with corticosteroids (exception: one dose of parenteral corticosteroids within the last 6 months, but not within the last 2 months, or an oral dose of prednisone of ≤ 10 mg/day for ≤ 2 weeks within the same period is allowed).

2. Pregnancy or wish to become pregnant during the study, or childbearing potential without adequate contraception.

3. Concomitant treatment with another experimental drug.

4. Bone marrow hypoplasia.

5. Elevated hepatic enzyme levels (aspartate transaminase [ASAT], alanine transaminase [ALAT] > 3 times normal value).

6. Serum creatinine levels > 150 umol/l or estimated creatinine clearance of < 75%.

7. Uncontrolled diabetes mellitus (according to the rheumatologist).

8. Uncontrolled hypertension (according to the rheumatologist).

9. Alcohol or drug abuse.

10. History of infected joint prosthesis within the previous 3 months.

11. Serious infections, such as hepatitis, pneumonia, pyelonephritis in the previous 3 months.

12. Chronic infectious disease such as chronic renal infection, chronic chest infection with

a. bronchiectasis or sinusitis.

13. History of opportunistic infections such as herpes zoster within previous 2 months.

14. Not being in the possession of a computer and/or not having access to the internet.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	07-03-2016
Enrollment:	141
Type:	Anticipated

Ethics review

Positive opinion

Date:	03-03-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44827
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5652
NTR-old	NTR5770
CCMO	NL52376.058.15
OMON	NL-OMON44827

Study results

Summary results
n/a