Conditioning and Health Training in Rheumatoid Arthritis

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20702

Bron
Nationaal Trial Register

Verkorte titel
EXPECT HEALTH

Aandoening

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.

Ondersteuning

Primaire sponsor: Leiden University
Overige ondersteuning: European Research Council Consolidator Grant

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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).

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	07-03-2016
Aantal proefpersonen:	141
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	03-03-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44827
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
n/a