Quality management: improvement of patient care in recently diagnosed rheumatoid arthritis.

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It is possible to increase the efficacy of treatment in early RA-patients with MTX when treatment is intensified according to a strict and intensive, computer-assisted protocol. I.e. the number of patients in remission will increase.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21292

Bron
NTR

Verkorte titel
CAMERA

Aandoening

Rheumatoid Arthritis is a chronic disease, characterized by inflammation and damage of several joints.

Ondersteuning

Primaire sponsor: Initator: UMC Utrecht, Department of Rheumatology & Clin. Immunology, on behalf of the Utrecht Rheumatoid Arthritis Cohort study group (SRU), a regional collaboration of departments of rheumatology in the region of Utrecht, The Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Number of patients in remission, in which remission is defined as:
-number of swollen joints = 0 plus at least
 two out of three following criteria:
-number of swollen joints <3
-ESR< 20 mm/hr1st
-VAS general well being < 20 mm

Toelichting onderzoek

Achtergrond van het onderzoek

Purpose:

To investigate whether intensive treatment with methotrexate (MTX) according to a strict protocol and a computerized decision program is more beneficial compared to conventional treatment with MTX in early rheumatoid arthritis (RA).

Methods:

In this multi-centre study, 301 patients with early rheumatoid arthritis were randomly assigned to the intensive strategy group or the conventional strategy group. Patients of both groups received MTX, the aim of treatment being remission. Patients of the intensive treatment group came to the outpatient clinic once every month; adjustment of the MTX dosage was tailored to the individual patient on the basis of predefined response criteria, using a computerized decision program. Patients of the conventional strategy group, who came to the outpatient clinic once every three months, were treated according to common practice.

Doel van het onderzoek

It is possible to increase the efficacy of treatment in early RA-patients with MTX when treatment is intensified according to a strict and intensive, computer-assisted protocol. I.e. the number of patients in remission will increase.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

In this study the efficacy of two treatment strategies will be compared: intensive treatment versus conventional treatment with MTX.
In both treatment strategy groups, patients will be treated with MTX. Starting dose MTX in both groups is 7.5 mg/wk.

In the intensive strategy group, based on predefined scores of disease activity with the help of a computer program, MTX will be increased to 15 mg/wk after 6 weeks. Thereafter, MTX is increased, if necessary, every 4 weeks by 5 mg/wk until a maximum dose of 30 mg/wk or until the maximum tolerable dose.

In the conventional treatment group, patients come to the outpatient clinic once every three months. In case of inefficient results of treatment after 3 months, dose MTX is increased until 15 mg/wk. After three months, dose MTX is increased by 5 mg/wk until a maximum of 30 mg/wk or maximum tolerable dose, if necessary. In both groups folinic acid (0.5 mg/day) is prescribed to all patients.

To patients with gastrointestinal side effects or with insufficient efficacy, MTX is given subcutaneaouly. Treatment with NSAIDS is allowed next to study medication. Oral glucocorticoids are not allowed during the trial unless unavoidable which has to be approved then by another rheumatologist. Intra-articular injections should be avoided as much as possible, and if necessary this should be mentioned.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. RA, defined according to the revised American College of Rheumatology (ACR) criteria for RA;

2. A disease duration of less than 1 year, estimated by the rheumatologist;

3. Age > 16 years;

4. No previous treatment with DMARDs;

5. Written informed consent by the patient.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Abnormal renal function (Cockroft < 75 ml/min.);

2. Abnormal liver function (ASAT/ALAT > 2* normal), active or recent hepatitis, cirrhose;

3. Major co morbidities like malignancies, severe diabetic mellitus, severe infections, severe cardio and/or respiratory diseases;

4. Leukopenia and/or thrombocytopenia;

5. Inadequate birth control conception, pregnancy, and / or breastfeeding;

6. Chronic use of oral glucocorticoids;

7. Treatment with cytoxic or immunosuppressive drugs within a period of 3 months prior to the study;

8. Alcohol intake >2 units per day or drug abuse, presently or in the past;

9. Psychiatric or mental disorders which makes adherence to the study protocol impossible;

10. Taking part into another clinical trial.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-1999
Aantal proefpersonen:	301
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	29-08-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL125
NTR-old	NTR158
Ander register	: N/A
ISRCTN	ISRCTN72821021

Resultaten

Samenvatting resultaten
Ann Rheum Dis. 2007 Nov;66(11):1443-9. Epub 2007 May 22

Verstappen SMM, Jacobs JWG, Bijlsma JWJ, Stichting Reumaonderzoek Utrecht(SRU). Computer Assisted Management of Early Rheumatoid Arthritis – CAMERA. Ned Tijdschr Reumatol 2004; 7 (suppl): 6. (abstract)

Verstappen S, Jacobs J, Bijlsma J, the Utrecht Rheumatoid Arthritis Cohort study group. Aiming for remission; Computer Assisted Management of Early Rheumatoid Arthritis: CAMERA. Arthritis Rheum 2004; 50 (suppl): S701. (abstract)