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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21292

Source
NTR

Brief title
CAMERA

Health condition

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

Sponsors and support

Primary 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

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. Disease activity during 1 year;

2. Feasibility of computer assisted program in daily practice.

Study description

Background summary

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.

Study objective

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.

Study design

N/A

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-1999
Enrollment:	301
Type:	Actual

Ethics review

Positive opinion

Date:	29-08-2005
Application type:	First submission

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
NTR-new	NL125
NTR-old	NTR158
Other	: N/A
ISRCTN	ISRCTN72821021

Study results

Summary results

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)