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

Submission date	Recruitment status
20/12/2005	No longer recruiting
Registration date	**Overall study status**
20/12/2005	Completed
Last Edited	**Condition category**
17/10/2007	Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
CAMERA

Study objectives
It is possible to increase the efficacy of treatment in early Rheumatoid Arthritis (RA)-patients with Methotrexate (MTX) when treatment is intensified according to a strict and intensive, computer-assisted protocol, i.e. the number of patients in remission will increase.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Rheumatoid arthritis

Interventions
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 subcutaneously. Treatment with Non-Steroidal Anti-Inflammatory Drugs (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.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Methotrexate

Primary outcome measure
Number of patients in remission, in which remission is defined as:
1. Number of swollen joints = 0
2. Plus at least two out of three following criteria:
2.1. Number of swollen joints less than 3
2.2. Erythrocyte Sedimentation Rate (ESR) less than 20 mm/hr
2.3. Visual Analogue Scale (VAS) general well being less than 20 mm

Secondary outcome measures
1. Disease activity during 1 year
2. Feasibility of computer assisted program in daily practice

Overall study start date
01/01/1999

Completion date
31/12/2003

Eligibility

Key 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. Aged greater than 16 years
4. No previous treatment with Disease Modifying Anti-Rheumatic Drugs (DMARDs)
5. Written informed consent by the patient

Participant type(s)

Patient

Age group
Adult

Sex
Both

Target number of participants
301

Key exclusion criteria
1. Abnormal renal function (Cockroft less than 75 ml/min)
2. Abnormal liver function (Aspartate Aminotransferase [ASAT]/Alanine Aminotransferase [ALAT] greater than 2 x normal), active or recent hepatitis, cirrhosis
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 greater than 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

Date of first enrolment
01/01/1999

Date of final enrolment
31/12/2003

Locations

Countries of recruitment
Netherlands

Study participating centre
UMC Utrecht
Utrecht
Netherlands
3508 GA

Sponsor information

Organisation
University Medical Centre Utrecht (UMCU) (Netherlands)

Sponsor details
PO Box 85500
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Sponsor type
University/education

Website
http://www.umcutrecht.nl/zorg/

ROR
https://ror.org/04pp8hn57

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	01/11/2007		Yes	No