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Early treatment of patients with undifferentiated arthritis (UA) with Methotrexate (MTX)

Submission date
12/09/2005

Recruitment status
No longer recruiting

Registration date
12/09/2005

Overall study status
Completed

Last Edited
19/08/2009

Condition category
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

NTR73

Study information

Scientific Title

Acronym
Probaat / PROMPT

Study objectives
We hypothesized that patients treated with Methotrexate (MTX) will have less duration and less severe arthritis, will not or less evolve into RA, will develop less radiographic progression in joint damage, and are more likely to go into remission.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from local medical ethics committee

Study design
Multicentre randomised double blind placebo controlled parallel group 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
Undifferentiated arthritis, probable rheumatoid arthritis according to ACR-1958 criteria

Interventions
The patients started with either 15 mg MTX or 6 placebo tablets.

Every three months the medication was increased with 5 mg or 2 tablets respectively if the disease activity score (DAS) was higher than 2,4. After 12 months, the study medication was phased out. If a patient is diagnosed with RA during the follow up, the treatment was continued with verum MTX. In case of side effects that might be related to MTX, the treatment was adjusted.

Patients were followed up for 18 months. At inclusion, 3, 6, 9, 12 and 18 months a tender and swollen joint count and health assessment questionnaires were performed and blood was donated for clinical and scientific research. Every 6 months radiographs of hands and feet were taken.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
Diagnosis after phasing out the study medication: rheumatoid arthritis, persisting undifferentiated arthritis or remission.

Secondary outcome measures
1. (Progression of) joint damage of hands and feet
2. Disease activity
3. Functional capacity

Overall study start date
01/03/2001

Completion date
01/06/2005

Eligibility

Key inclusion criteria
1. Diagnosis probable RA according to the ACR-1958 criteria
2. Aged 18 years or older
3. Less than 2 years of complaints
4. No DMARD use in the past (except Prednisone, maximal 3 months)
5. Signed informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
110

Key exclusion criteria
1. Diagnosis RA according to the ACR-1987 criteria
2. Kidney disorder: creatinine >150umol/l or estimated clearance < 75
3. Liver function disorder: ASAT, ALAT > 3x normal values
4. Alcoholism
5. Bone marrow insufficiency
6. Pregnant or pregnancy wish during study or 3 months thereafter
7. No adequate method of birth control

Date of first enrolment
01/03/2001

Date of final enrolment
01/06/2005

Locations

Countries of recruitment
Netherlands

Study participating centre
Leiden University Medical Center
Leiden
Netherlands
2333 ZA

Sponsor information

Organisation
Leiden University Medical Center (LUMC) (Netherlands)

Sponsor details
Albinusdreef 2
P.O. Box 9600
Leiden
Netherlands
2300 RC

Sponsor type
Hospital/treatment centre

ROR

https://ror.org/05xvt9f17

Funder(s)

Funder type
Charity

Funder Name
Dutch Arthritis Association (Reumafonds) (Netherlands)

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	01/05/2007		Yes	No