

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

Submission date 12/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 12/09/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 19/08/2009	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

ROR
<https://ror.org/05xvt9f17>

Funder(s)

Funder type
Charity

Funder Name
Dutch Arthritis Association (Reumafonds) (Netherlands)

Results and Publications

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