

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

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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