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

No registrations found.

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

Summary

ID

NL-OMON23294

Source
Nationaal Trial Register

Brief title
PROMPT/Probaat

Intervention

Outcome measures

Primary outcome

The primary outcome is diagnosis after phasing out the study medication: rheumatoid arthritis, persisting undifferentiated arthritis or remission.

Secondary outcome

Secondary outcome values are (progression of) joint damage of hands and feet, disease activity and functional capacity.

Study description

Background summary

In patients with RA many studies have demonstrated the benefit of early initiation of Disease Modifying Anti-Rheumatic Drugs (DMARDs), resulting in a better prognosis. Patients included in these studies generally fulfilled the 1987 ACR classification criteria for RA. Although RA patients benefit from early aggressive treatment, it is unknown whether UA patients who might evolve into RA will also benefit from such a treatment strategy. In the present study, patients with undifferentiated arthritis fulfilling the ACR 1958 criteria for probable RA were treated with either methotrexate or placebo. We hypothesized that patients treated with 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.

Study objective

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.

Study design

N/A

Intervention

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.

Contacts

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Eligibility criteria

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.

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2001
Enrollment:	110
Type:	Actual

Ethics review

Positive opinion

Date:	27-06-2005
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	NL44
NTR-old	NTR73
Other	: N/A
ISRCTN	ISRCTN21334657

Study results

Summary results
Arthritis Rheum. 2007 May;56(5):1424-32.