Strategies in early arthritis management.

No registrations found.

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

Summary

ID

NL-OMON25364

Source
NTR

Brief title
STREAM

Health condition

rheumatoid arthritis, undifferentiated oligo- or polyarthritis

Sponsors and support

Primary sponsor: Prof dr BAC Dijkmans
VUmc
Source(s) of monetary or material Support: This study is supported by Abbott

Intervention

Outcome measures

Primary outcome

Progression of radiographic damage score after 2 years.

Secondary outcome

1. Functional capacity;
2. Quality of life;

3. Disease activity.

Study description

Background summary

There are indications that patients with mild early arthritis are undertreated with joint damage as a consequence. Therefore, we have designed a trial to test the hypothesis that a treatment strategy aimed at achieving and maintaining remission with (a combination of) disease modifying antirheumatic drugs including adalimumab leads to less joint damage than the usual care in patients with early, mild arthritis. In the active group, treatment is switched on the basis of a disease activity score (DAS44), which should become and remain under 1.6. The study duration is 2 years per patient.

Study objective

After 2 years of treatment with a combination of antirheumatic drugs including adalimumab with the aim of achieving and maintaining remission in patients with mild arthritis, there is less radiographic progression than in patients treated with ususal care.

Study design

N/A

Intervention

Methotrexate, in case of insufficient response followed by adalimumab, and then by a combination of methotrexate, sulfasalazine, hydroxychloroquin and prednisone versus usual care according to preference physician.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age 18+;

2. Symptom duration less than 3 years;

3. Swelling 2-5 joints.

Exclusion criteria

1. Earlier treatment with disease modifying antirheumatic drugs except hydrxychloroquine;

2. Prednisone use within 3 months;

3. Bacterial arthritis, crystal induced arthritis, reactive arthritis, sarcoidosis, osteoarthritis or systemic autoimmune disease other than RA;

4. Pregnancy;

5. Erosive disease.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2004
Enrollment:	80
Type:	Actual

Ethics review

Positive opinion

Date:	24-08-2005
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	NL113
NTR-old	NTR144
Other	: N/A
ISRCTN	ISRCTN56637846

Study results

Summary results
N/A