

STRategies in Early Arthritis Management

Submission date 20/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 20/12/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 17/12/2008	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title

Acronym
STREAM

Study objectives

After 2 years of treatment with a combination of anti-rheumatic 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 usual care.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the local medical ethics committee

Study design

Randomised single blind active controlled parallel group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Polyarthritis/rheumatoid arthritis

Interventions

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

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Adalimumab, methotrexate, sulfasalazine, hydroxychloroquine, prednisone

Primary outcome(s)

Progression of radiographic damage score after 2 years.

Key secondary outcome(s)

1. Functional capacity
2. Quality of life
3. Disease activity

Completion date

01/07/2007

Eligibility

Key inclusion criteria

1. Aged 18+ years
2. Symptom duration less than 3 years
3. Swelling in two to five joints

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Earlier treatment with disease modifying antirheumatic drugs except hydroxychloroquine
2. Prednisone use within 3 months
3. Bacterial arthritis, crystal induced arthritis, reactive arthritis, sarcoidosis, osteoarthritis or systemic autoimmune disease other than rheumatoid arthritis (RA)
4. Pregnancy
5. Erosive disease

Date of first enrolment

01/07/2004

Date of final enrolment

01/07/2007

Locations**Countries of recruitment**

Netherlands

Study participating centre

Jan van Breemen Instituut

Amsterdam

Netherlands

1056 AB

Sponsor information

Organisation

Jan van Breemen Institute (Netherlands)

ROR

<https://ror.org/00bp9f906>

Funder(s)**Funder type**

Industry

Funder Name

Abbott (Netherlands) - study is investigator driven

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration