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STRategies in Early Arthritis Management

Submission date	Recruitment status	[ ] Prospectively registered
20/12/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/12/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
17/12/2008	Musculoskeletal Diseases	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Progression of radiographic damage score after 2 years.

Secondary outcome measures
1. Functional capacity
2. Quality of life
3. Disease activity

Overall study start date
01/07/2004

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80

Key exclusion criteria
1. Earlier treatment with disease modifying antirheumatic drugs except hydroychloroquine
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)

Sponsor details
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Sponsor type
Research organisation

Website
http://www.janvanbreemen.nl

ROR
https://ror.org/00bp9f906

Funder(s)

Funder type
Industry

Funder Name
Abbott (Netherlands) - study is investigator driven

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