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RheumAFooT (Rheumatoid Arthritis Foot Trial)

Submission date	Recruitment status	[X] Prospectively registered
14/08/2003	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/08/2003	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
22/11/2007	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
G108/397

Study information

Scientific Title

Acronym
RheumAFooT

Study objectives
The aim of this trial is to compare podiatry with no podiatry footcare in rheumatoid arthritis (RA) patients with painful and disabling foot symptoms.

The objectives are:
Primary objective: To compare foot health status (activities, impairment, participation and shoe) between active and control groups using the Leeds Foot Impact Scale.
Secondary objective 1: To compare foot function (spatial and temporal gait parameters) between the two groups using instrumented gait analysis.
Secondary objective 2: To test whether the effect of podiatry, as measured by Leeds Foot Impact Scale, is correlated with patient sex, disease duration and degree of initial foot health status.
Secondary objective 3: To determine the cost effectiveness of podiatry care for RA related foot problems.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration.

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Rheumatoid arthritis

Interventions
Active treatment arm: 12 months podiatry care
Control treatment arm: 12 months

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Primary outcome: change in Leeds Foot Impact Scale score between baseline and 12 months.

Key secondary outcome(s)
Disease activity score, health assessment questionnaire and walking speed were also recorded.

Completion date
30/09/2005

Eligibility

Key inclusion criteria
Patients will be suitable for inclusion if they have a definite diagnosis of RA (satisfying the 1987 American Rheumatism Association revised criteria for RA), are between 18-80 years of age and can read and write English. Patients must also have a current history of foot impairment as determined by standard history and clinical examination techniques and a Leeds Foot Impact Scale score of ≥15 points. Patients must also have stable drug management in the 3 months prior to recruitment including Disease Modifying Anti-Rheumatic Drugs, Non-Steroidal Anti-Inflammatory Drugs and oral corticosteroids.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
All

Key exclusion criteria
Patients will be excluded if they have foot problems related to and require treatment under the appropriate medical specialty such as diabetes and peripheral vascular disease. Patients will be excluded if they have severe complications of their RA resulting in active or high risk of developing foot ulceration. On medical consultation, any patient with foot problems, such as ulceration and infection, likely to complicate systematic treatment with biologic and other immunosuppressant therapy (Infliximab, Etanercept, Anakinra, Cyclophosphamide, Cyclosporin, Azathioprine and any new, including trial, biologic - even if placebo) will be excluded. Those patients who have received podiatry treatment at Leeds General Infirmary Foot Health Department in the last 3 months will also be excluded.

Date of first enrolment
01/10/2003

Date of final enrolment
30/09/2005

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Academic Unit of Musculoskeletal Disease
Leeds
United Kingdom
LS2 9NZ

Sponsor information

Organisation
Medical Research Council (UK)

Funder(s)

Funder type
Government

Funder Name
Medical Research Council (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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	06/11/2007		Yes	No