

RheumAFooT (Rheumatoid Arthritis Foot Trial)

Submission date 14/08/2003	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 18/08/2003	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 22/11/2007	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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.

Study design

Randomised controlled trial

Primary study design

Interventional

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