A randomised controlled trial investigating the efficacy of foot orthoses in rheumatoid arthritis (RA)

Submission date 18/07/2002	Recruitment status No longer recruiting
Registration date 18/07/2002	Overall study status Completed

Last Edited 16/09/2009 Condition category Musculoskeletal Diseases

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Prospectively registered

[] Protocol

[] Statistical analysis plan

[X] Results

[] Individual participant data

Study information

Scientific Title

Study objectives

A common rearfoot problem in rheumatoid arthritis is the progressive development of valgus heel deformity. This condition is underdiagnosed and management strategies generally employed at a late stage when secondary features have developed and the deformity is uncorrectable. The mechanical cause of valgus heel deformity is excessive subtalar pronation during the contact phase of gait. Foot orthoses used by podiatrists have been shown to correct pronation but their use has not been formally evaluated in rheumatoid arthritis. The aim of this study is to evaluate the effectiveness of foot orthoses in preventing valgus heel deformity and preventing secondary features.

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

Secondary study design Randomised controlled trial

Study setting(s) Other

Study type(s) Prevention

Participant information sheet

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

Interventions

Patients with RA were randomised to receive custom manufactured rigid foot orthoses under podiatry supervision or enter a control group.

The control group received foot orthoses only when prescribed under normal medical care.

Intervention Type

Other

Phase Not Specified

Primary outcome measure

1. Video gait analysis

2. Dynamic load measurements

3. Pain and disability assessment

Evaluation of disease status will be mapped for patients over a 60 month period. Appropriate comparative analyses will be made.

Secondary outcome measures

Not provided at time of registration

Overall study start date 11/01/1996

Completion date 10/01/2000

Eligibility

Key inclusion criteria

1. Current history of bilateral subtalar ± ankle ± talonavicular pain, and valgus heel deformity

2. Normal range of motions was required at the ankle, subtalar and midtarsal joints

3. Passive range of motion testing was used to ensure the valgus heel deformity was correctable with 10 degrees of subtalar joint inversion past neutral

Participant type(s)

Patient

Age group Not Specified

Sex Not Specified

Target number of participants 98

Key exclusion criteria Does not meet inclusion criteria

Date of first enrolment 11/01/1996

Date of final enrolment 10/01/2000

Locations

Countries of recruitment England

United Kingdom

Study participating centre Rheumatology & Rehabilitation Research Unit Leeds United Kingdom LS2 9NZ

Sponsor information

Organisation Arthritis Research Campaign (ARC) (UK)

Sponsor details

Copeman House St Mary's Court St Mary's Gate Chesterfield Derbyshire United Kingdom S41 7TD -

info@arc.org.uk

Sponsor type Charity

Website http://www.arc.org.uk

ROR https://ror.org/02jkpm469

Funder(s)

Funder type Charity

Funder Name

Arthritis Research Campaign (ARC) (UK)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Results article</u>	results	01/07/2002		Yes	No