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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

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
W0542

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
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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?
Results article	results	01/07/2002		Yes	No