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A randomised controlled trial investigating the effect of debridement of painful and disabling forefoot plantar callosities and corns in rheumatoid arthritis.

Submission date
30/09/2004

Recruitment status
No longer recruiting

Registration date
30/09/2004

Overall study status
Completed

Last Edited
06/10/2009

Condition category
Skin and Connective Tissue 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

Contact name
Miss H J Davys

Contact details
Foot Health Department, B Floor
Brotherton Wing
Leeds Teaching Hospitals NHS Trust
Great George Street
Leeds
United Kingdom
LS1 3EX
+44 (0)113 3923558
r&d@leedsth.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0436130647

Study information

Scientific Title

Study objectives
Primary aim: to investigate the immediate (same day) and subsequent daily effects of expert scalpel debridement of symptomatic forefoot plantar callosities and corns on forefoot pain in rheumatoid arthritis.

Secondary aims: to evaluate and compare the results of plantar pressure measurement following expert scalpel debridement of forefoot symptomatic lesions in RA patients using high-resolution pressure platform and in-shoe measurement systems. To estimate associated risks (adverse reactions) of treatment including episodes of immediate discomfort post intervention, localized bleeding or ulceration at treated lesion sites. A retrospective review of forefoot pathology determined by x-ray including deformity and extent of erosions for cases where existing films are available.

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)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Corns and collosites in rheumatoid arthritis (RA)

Interventions

Randomised controlled trial. Random allocation to
1. Scalpel debridement
2. Sham proceedure using blunt scalpel

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Foot pain visual analogue scales, Leeds Foot Impact Scale.
2. Spatial & temporal parameters using GaitRite system
3. Plantar pressure measurement using Novel Pedar in-shoe system an emed-sf platform.
4. Individual Larsen score for each metatarsophalangeal (MTP) joint.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/2003

Completion date
01/03/2004

Eligibility

Key inclusion criteria
Patients with a positive diagnosis of rheumatoid arthritis (American College of Rheumatology [ACR] classification 1987) and symptomatic forefoot plantar corns and callosities.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
38 (added 06/10/09)

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/09/2003

Date of final enrolment

01/03/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Foot Health Department, B Floor
Leeds
United Kingdom
LS1 3EX

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Leeds Teaching Hospitals NHS Trust (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	01/02/2005		Yes	No