

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	<input type="checkbox"/> Prospectively registered
Registration date 30/09/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 06/10/2009	Condition category Skin and Connective Tissue 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
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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 procedure using blunt scalpel

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

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.

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre

Foot Health Department, B Floor

Leeds

United Kingdom

LS1 3EX

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Leeds Teaching Hospitals NHS Trust (UK)

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	01/02/2005		Yes	No