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The CARROT trial: CAllus Reduction Reinforcing Orthotic Therapy

Submission date	Recruitment status
01/10/2007	No longer recruiting
Registration date	**Overall study status**
15/05/2008	Completed
Last Edited	**Condition category**
04/03/2013	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

Protocol serial number
PB-PG-0706-10143

Study information

Scientific Title
The CARROT trial: CAllus Reduction Reinforcing Orthotic Therapy - the effectiveness of sharp scalpel debridement of callus as a component of complex long-term interventions for painful forefoot plantar callosities in patients with rheumatoid arthritis

Acronym
CARROT

Study objectives
This is a randomised controlled trial (RCT) of patients with rheumatoid arthritis (RA) and painful forefoot plantar callosities receiving either debridement of painful forefoot plantar callosities plus conservative therapies or conservative therapies alone.

Hypothesis:
The addition of repeated sharp scalpel debridement of callus to a long-term care plan offers no greater reduction in pain or improvement in functional status than a low-risk, long-term care plan based on conservative self care, footwear advice, padding and/orthoses.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Leeds (West) Research Ethics Committee on the 30th May 2007 (ref: 07/Q1205/70).

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Conservative long-term therapies:
Usual conservative long-term therapies will be provided to patients in both the treatment and control arms. Long-term therapies include education and self-management advice, footwear advice, prescription of foot orthoses, referral for orthopaedic footwear, referral to physiotherapy, and intra-articular and soft tissue injection therapy. Patients in the control arm will receive the long-term therapeutic protocol only, while patients in the treatment arm will receive the long-term therapeutic protocol plus sharp scalpel debridement of callosities.

Callus debridement:
Patients in the treatment arm will receive repeat callus debridement in addition to the standard long-term therapy. Debridement will involve regular removal of the callused lesions with a scalpel. The intervals between debridement will be determined by the clinician according to a debridement protocol, and may be altered during the course of the study dependent upon the requirements of the individual patient.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Forefoot pain measured by 100 mm Visual Analogue Scale (VAS) and the pain subscale of the Foot Function Index (FFI). Patients in both treatment arms will complete pain scores at 6, 12 and 18 weeks (± 2 weeks); and at 6, 9, 12 and 18 months (± 1 month). The Leeds Foot Impact Scale (LFIS) will be used to measure the impact of foot pain, impairment, activity limitation and footwear at baseline, 6 and 12 months and at exit (18 months).

Key secondary outcome(s))
1. Intra-operative haemorrhage, measured at 6, 12 and 18 weeks (± 2 weeks) and at 6, 9, 12 and 18 months (± 1 month)
2. Post-treatment infection and ulceration rates, measured at 6, 12 and 18 weeks (± 2 weeks) and at 6, 9, 12 and 18 months (± 1 month)
3. Number of clinical appointments required, measured at 6, 12 and 18 weeks (± 2 weeks) and at 6, 9, 12 and 18 months (± 1 month)
4. Temporal and spacial parameters of gait (measured at baseline and exit visit only) and forefoot plantar pressures, measured at 6, 12 and 18 weeks (± 2 weeks) and at 6, 9, 12 and 18 months (± 1 month)

Completion date
15/10/2010

Eligibility

Key inclusion criteria
1. Positive diagnosis of RA (American Rheumatology Association [ARA]/American College of Rheumatology [ACR] classification 1987)
2. One or more painful forefoot plantar callosities (including corns)
3. Willingness to participate in trial for 18 months
4. Participants aged more than or equal to 16, male and female

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria

1. Co-morbidity which would place the patient at risk if randomised to the control arm, e.g. diabetes mellitus, peripheral arterial insufficiency, loss of protective sensation, existing risk /presence of ulceration/extravasation at baseline
2. History of routine podiatric intervention including callus debridement on two or more occasions in the previous 12 months

Date of first enrolment
15/10/2007

Date of final enrolment
15/10/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Leeds
Leeds
United Kingdom
LS2 9NZ

Sponsor information

Organisation
Leeds Teaching Hospital NHS Trust (UK)

ROR
https://ror.org/00v4dac24

Funder(s)

Funder type
Government

Funder Name
Department of Health (UK) - Research for Patient Benefit Scheme

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	01/05/2013		Yes	No