

The CARROT trial: Callus Reduction Reinforcing Orthotic Therapy

Submission date 01/10/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 15/05/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 04/03/2013	Condition category Musculoskeletal 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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).

Secondary outcome measures

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)

Overall study start date

15/10/2007

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

64

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**

England

United Kingdom

Study participating centre

University of Leeds

Leeds

United Kingdom

LS2 9NZ

Sponsor information**Organisation**

Leeds Teaching Hospital NHS Trust (UK)

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<http://www.leedsteachinghospitals.com/>

ROR

<https://ror.org/00v4dac24>

Funder(s)**Funder type**

Government

Funder Name

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

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	01/05/2013		Yes	No