

Do stretching exercises reduce plantar pressure in the at-risk diabetic foot?

Submission date

12/09/2003

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

12/09/2003

Overall study status

Completed

☐ Statistical analysis plan

☐ Results

Last Edited

03/01/2020

Condition category

Nutritional, Metabolic, Endocrine

☐ Individual participant data

☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Ms Sue Pyle

Contact details

Royal Devon & Exeter Hospital (Wonford)

Barrack Road

Exeter

United Kingdom

EX2 5BW

+44 (0)1392 402204

hf@cct.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0203121474

Study information

Scientific Title

-

Study objectives

As limited joint movement does not affect the joints directly but rather the soft tissues surrounding them, we hypothesise that mobilisation techniques may prevent some of the destructive, pathomechanical forces initiated by joint limitation.

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

Nutritional, Metabolic, Endocrine: Diabetes

Interventions

A pilot pragmatic, randomised control trial will be undertaken to assess the effect of teaching stretching exercises to patients with limited joint movement. The primary outcomes will be the improvement in the range of movement and a reduction in the peak plantar pressure.

Measurement of range of movement and plantar pressure will be taken monthly; 50% of recruits will be required to follow a set exercise programme twice weekly, for a total of 12 weeks.

Patients will be contacted fortnightly to monitor progress.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

This is a pilot study that aims to provide preliminary data to test the hypothesis that regular stretching exercises of the foot and ankle will reduce the risk of ulceration in diabetic, neuropathic feet by improving the range of movement of the ankle and hence lower peak plantar pressures. We will evaluate using a randomised control study of a home treatment plan where diabetic patients with neuropathy and limited joint mobility are taught to use regular stretching exercises.

Study endpoints: To assess if this treatment (compared to no treatment):

1. Increases the range of movement at the ankle joint
2. Reduces peak plantar pressure

Secondary outcome measures

Not provided at time of registration

Overall study start date

27/01/2003

Completion date

31/10/2003

Eligibility

Key inclusion criteria

1. Diabetic subjects attending the Diabetes and Vascular Centre and local chiropody clinics will be considered for the trial
2. Over 35 years of age
3. Diabetes mellitus
4. Peripheral sensory neuropathy

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

Not provided at time of registration

Key exclusion criteria

1. Arthritic conditions (e.g., osteo/rheumatoid)
2. Partial amputation
3. Previous severe trauma (fracture/tendon rupture/charcots)
4. Excessive scar tissue
5. Surgical intervention

6. Severe gait disturbance
7. Peripheral vascular disease (PVD)
8. Known collagen disorders

Date of first enrolment

27/01/2003

Date of final enrolment

31/10/2003

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Royal Devon & Exeter Hospital (Wonford)

Exeter

United Kingdom

EX2 5BW

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

Royal Devon and Exeter 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