The effectiveness of manipulation therapy on joint mobility in the 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 19/07/2017 | 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N0226114890

Study information

Scientific Title The effectiveness of manipulation therapy on joint mobility in the diabetic foot

Study objectives

To investigate the effectiveness of manipulation therapy in improving joint mobility in the diabetic foot; to determine the range of motion at the first metatarso-phalangeal joint and ankle joint before and after manipulation therapy; to determine plantar foot pressures before and after manipulation therapy.

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 and endocrine diseases: Diabetic foot ulcer

Interventions

Patients randomised to both the study and control groups will have the range of motion at the 1st metatarso-phalangeal and ankle joint measured.

The study group will then have the manipulation therapy.

In the control group, patients will have joint mobility and foot pressure measurements at 6 weeks apart, with option for manipulation therapy after completion of the study.

Intervention Type

Other

Phase Not Specified

Primary outcome measure

Change in joint mobility at first metatarso-phalangeal and ankle joint after manipulation treatment.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/04/2003

Completion date 01/04/2004

Eligibility

Key inclusion criteria

12 patients (attending the MFH, MDC, DSC and community podiatry clinics) with a positive prayer sign, neuropathy disability score of >6, presence of at least one foot pulse.

Participant type(s) Patient

Age group Not Specified

Sex Not Specified

Target number of participants 12

Key exclusion criteria Not provided at time of registration

Date of first enrolment 01/04/2003

Date of final enrolment 01/04/2004

Locations

Countries of recruitment England

United Kingdom

Study participating centre

South Manchester University Hospitals NHS Trust Manchester United Kingdom M20 2LR

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 South Manchester University 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