

A randomised controlled trial examining the effectiveness of acupuncture in the treatment of lower limb painful neuropathy in diabetes

Submission date 30/07/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 30/07/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 25/03/2014	Condition category Nutritional, Metabolic, Endocrine	<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

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

5113

Study information

Scientific Title

Acronym

DRN196 (Acupuncture in Painful Diabetic Neuropathy)

Study objectives

The hypothesis of the study will be that acupuncture treatment will be additional benefit to patients suffering from lower limb painful diabetic neuropathy when compared to a control group.

Ethics approval required

Old ethics approval format

Ethics approval(s)

MREC approved (ref: 08/H1011/16A)

Study design

Single centre randomised interventional process of care treatment trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Topic: Diabetes Research Network; Subtopic: Both; Disease: Neuropathy

Interventions

Acupuncture

Intervention Type

Other

Phase

Phase IV

Primary outcome measure

Pain relief

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/06/2008

Completion date

21/05/2010

Eligibility

Key inclusion criteria

1. Type 1 and type 2 diabetes
2. Aged between 18 - 80 years
3. Presence of diabetic neuropathy
4. Painful neuropathy
5. Receiving treatment for PDN
7. Can attend once a week for 10 weeks

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

Planned sample size: 60; UK sample size: 60

Key exclusion criteria

1. Painful neuropathy attributed to other conditions other than diabetes
2. Patients with poor peripheral circulation
3. Patients with an active foot ulcer
4. Patients who have had previous acupuncture treatment

Date of first enrolment

01/06/2008

Date of final enrolment

21/05/2010

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Fountain Street

Ashton-under-Lyne

United Kingdom

OL6 9RW

Sponsor information

Organisation

Tameside Hospital NHS Foundation Trust (UK)

Sponsor details

Tameside General Hospital

Fountain Street

Ashton-under-Lyne

England

United Kingdom

OL6 9RW

Sponsor type

Hospital/treatment centre

Website

<http://www.tamesidehospital.nhs.uk/pages/default.asp>

ROR

<https://ror.org/04d713p41>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) programme (ref: PB-PG-0706-10595)

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	01/06/2014		Yes	No