

Effect of acupuncture using the HeSantong method on diabetic peripheral neuropathy

Submission date 27/12/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 17/02/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 02/09/2020	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Diabetic peripheral neuropathy (DPN) is a common complication of diabetes, which may lead to diabetic foot ulcers and foot or limb amputations. It is commonly treated by acupuncture. There are many published cases reports showing that acupuncture works for DPN. More in-depth research is needed and this is the aim of this study (Wentong Method of Hesantong Method based on Hesantong Method developed by Professor He Puren).

Who can participate?

Participants diagnosed with DPN.

What does the study involve?

Participants are randomly allocated to one of two groups: Wentong Method/Hesantong Method group or Shallow acupuncture at sham points group. Participants undergo a number of tests before and after the 8-week treatment.

What are the possible benefits and risks of participating?

Participants may experience infection, hematoma, syncope, discomfort after the acupuncture.

Where is the study run from?

BeiJing Hospital of Traditional Chinese Medicine affiliated to Capital Medical University (China)

When is study starting and how long is it expected to run for?

August 2013 to July 2015.

Who is funding the study?

BeiJing Hospital of Traditional Chinese Medicine affiliated to Capital Medical University (China)

Who is the main contact?

Professor Yi Jinghong
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Contact information

Type(s)

Scientific

Contact name

Prof Jinghong Yi

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information**Scientific Title**

Effect of acupuncture using the HeSantong method on diabetic peripheral neuropathy: a randomised controlled trial

Study objectives

1. The Wentong method and HeSantong method are both specific and holistic. This non-drug therapy has tremendous potential and is likely to treat diabetic peripheral neuropathy as expected.
2. Objective and comprehensive evaluating indexes can improve the credibility of acupuncture using the Wentong method and the HeSantong method on diabetic peripheral neuropathy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of Beijing Hospital of Traditional Chinese Medicine affiliated to Capital Medical University, 29/11/2013, ref. 2013BL-085-01

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

Diabetic Peripheral Neuropathy

Interventions

Patients are randomised to receive the following treatments:

1. Acupuncture using the Wentong method and the Hesantong method

Main points: Yanglingquan, Zusanli, Taixi, Ashi points

Needling method: Wentong Method and HeSantong method

Treating course: treatment given twice a week for 8 weeks as one course of treatment

2. Shallow acupuncture at sham points

Points: sham meridians and points

Needling method: Shallow acupuncture at sham points

Treating course: treatment given twice a week for 8 weeks as one course of treatment

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Traditional Chinese medicine (TCM) syndrome score at baseline, after treatment for 4 and 8 weeks, and after 4 weeks of completing the treatment

2. Nerve electrophysiological examination at baseline and after 8 weeks treatment

Secondary outcome measures

MDNS at baseline, after treatment for 4 and 8 weeks and after 4 weeks of completing the treatment

Overall study start date

01/08/2013

Completion date

31/07/2015

Eligibility

Key inclusion criteria

1. Patient has diabetic peripheral neuropathy
2. Patient aged 18 to 70 years
3. Michigan diabetic neuropathy score (MDNS) of 7 to 29
4. Fasting blood glucose (FBG) less than or equal to 8.0mmol/L, Postprandial Plasma Glucose (PPG) less than or equal to 11.0 mmol/L
5. Patient providing informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

60

Key exclusion criteria

1. Patient suffering from acute complications of diabetes within one month
2. Patients with spinal cord injury, spinal deformity, stroke sequela and neuromuscular disorders or peripheral neuropathy caused by other factors (such as heredity, alcoholism, uremia, infection, malnutrition, drug intoxication and metal intoxication)
3. Patient having epilepsy or mental illness
4. Patient having arteriovenous disease
5. Patient having the following complications: serious primary diseases of other systems, abnormal liver and kidney function, overwhelming infection or advanced tumor
6. Dipsomanias
7. Drug abuse over the past five years or been exposed to chemical poisons

Date of first enrolment

01/08/2013

Date of final enrolment

31/07/2015

Locations

Countries of recruitment

China

Study participating centre

Beijing Hospital of Traditional Chinese Medicine affiliated to Capital Medical University

Beijing

China

100010

Sponsor information

Organisation

Beijing Hospital of Traditional Chinese Medicine Affiliated to Capital Medical University (China)

Sponsor details

c/o Jinghong YI

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Dong Cheng District

Beijing

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100010

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/057vq6e26>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Beijing Hospital of Traditional Chinese Medicine affiliated to Capital Medical University (China)

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