

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Effectiveness of acupuncture treatment on chemotherapy induced peripheral neuropathy: a pilot randomized controlled trial

#### Protocol summary

##### Study aim

The aim of this study is to evaluate the effectiveness and safety of acupuncture in treatment of chemotherapy-induced peripheral neuropathy.

##### Design

Parallel, pilot randomized controlled trial with blinded outcome assessment

##### Settings and conduct

The study will be conducted on 40 patients with diagnosis of chemotherapy induced peripheral neuropathy referred to Dongzhimen Hospital affiliated to Beijing University of Chinese Medicine, and Imam Khomeini Hospital affiliated to Tehran University of Medical Science, that will be randomly assigned to acupuncture or vit B1 and gabapentin groups.

##### Participants/Inclusion and exclusion criteria

Eligible participants are patients with age between 18 and 70 years, who have received neurotoxic chemotherapy, have experienced symptoms of chemotherapy-induced peripheral neuropathy for more than three months, have scores  $\geq 4$  on 10 on the Numerical Rating Scale. Patients are not to use medication for prevention or treatment of neuropathy for at least one month before enrollment. Exclusion criteria include diabetes, multiple sclerosis, HIV, Parkinson, alcohol abuse, pregnancy, psychological disease, and severe dysfunction of the heart, kidneys or liver.

##### Intervention groups

Patients in the acupuncture group will be received twelve sessions (over 4 weeks) of acupuncture. Control group will be taken one tablet of vit B1 300 mg (Jalinous and GNC pharmaceutical companies) and three capsules of gabapentin 300 mg (Abidi and Jiangsu Enhua pharmaceutical companies) per day for 4 weeks, after which both groups will be followed up for 4 weeks.

##### Main outcome variables

Chemotherapy induced peripheral neuropathy symptom severity, grade of sensory neuropathy, severity of neuropathy, patient overall satisfaction with treatment,

safety assessment and adverse events.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190615043900N1**

Registration date: **2019-06-29, 1398/04/08**

Registration timing: **retrospective**

Last update: **2019-06-29, 1398/04/08**

Update count: **0**

##### Registration date

2019-06-29, 1398/04/08

##### Registrant information

##### Name

Somayeh Iravani

##### Name of organization / entity

Beijing University of Chinese Medicine

##### Country

China

##### Phone

+86 10 5391 2012

##### Email address

iravani\_somayeh@bucm.edu.cn

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-06-22, 1396/04/01

##### Expected recruitment end date

2018-11-22, 1397/09/01

##### Actual recruitment start date

2017-06-22, 1396/04/01

##### Actual recruitment end date

2018-11-22, 1397/09/01

**Trial completion date**

2018-12-22, 1397/10/01

**Scientific title**

Effectiveness of acupuncture treatment on chemotherapy induced peripheral neuropathy: a pilot randomized controlled trial

**Public title**

Effectiveness of acupuncture in treatment of chemotherapy induced peripheral neuropathy

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients with age between 18 and 70 years Who have received neurotoxic chemotherapy (at least one complete course) Have experienced symptoms of chemotherapy-induced peripheral neuropathy for more than three months Have scores  $\geq 4$  on 10 on the Numerical Rating Scale (NRS) Accept and sign an informed consent form Patients were also not to use medications such as Tricyclic antidepressants (TCA), calcium channel blockers, and membrane stabilizing drugs for the prevention or treatment of the neuropathy for at least one month before enrollment

**Exclusion criteria:**

History of disease that causes neuropathy, such as diabetes, multiple sclerosis, HIV, and Parkinson The presence of peripheral neuropathy or history of peripheral neuropathy due to any cause excluding chemotherapy Alcohol abuse Pregnancy Psychological disease Severe dysfunction of the heart, kidneys, or liver

**Age**

From **18 years** old to **70 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **40**

Actual sample size reached: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Eligible participants will be randomized in a ratio of 1:1 to either the acupuncture group or control group. A block randomization list will be created by the 'blockrand' package in R software (version 3.3.3), based on n=40 participants and two treatments. The allocation sequence will be concealed from the researchers in sealed, opaque and sequentially numbered envelopes. After the researcher has assessed eligibility, obtained the participant's consent, and completed all baseline evaluations of the participants, corresponding envelopes will be opened and treatment allocation will be revealed.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

In acupuncture research, it is not possible to blind the practitioner, and in this study participants are also aware of the type of treatment because one group receive acupuncture and the other group receive pharmacological medication, and it is not feasible to blind participants. But treatment and evaluation will be performed independently. Subjective and objective evaluations and statistical analysis will be performed by blinded specialists, who are not aware of the allocation of participants.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee Board of Beijing University of Chinese Medicine

**Street address**

No.11, 3rd North Ring Road, Chaoyang District

**City**

Beijing

**Postal code**

100029

**Approval date**

2017-06-20, 1396/03/30

**Ethics committee reference number**

2017BZHYLL0317

**2****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Science

**Street address**

6th floor, central building, Qods street, Keshavarz Blvd

**City**

Tehran

**Province**

Tehran

**Postal code**

1417614418

**Approval date**

2018-08-20, 1397/05/29

**Ethics committee reference number**

IR.TUMS.VCR.REC.1397.362

## Health conditions studied

### 1

#### Description of health condition studied

Chemotherapy-induced Peripheral Neuropathy

#### ICD-10 code

G62.0

#### ICD-10 code description

Drug-induced polyneuropathy

## Primary outcomes

### 1

#### Description

Chemotherapy induced peripheral neuropathy symptom severity

#### Timepoint

Before treatment, 2 and 4 weeks after starting treatment, as well as 4 weeks after the end of treatment (after 8 weeks)

#### Method of measurement

Chemotherapy induced peripheral neuropathy symptom severity will be assessed by asking patients to rate their average neuropathic symptoms, such as tingling, numbness and pain, on an 11-point scale (Numerical Rating Scale) over the course of a particular day.

## Secondary outcomes

### 1

#### Description

Grade of sensory neuropathy

#### Timepoint

Before treatment, 2 and 4 weeks after starting treatment, as well as 4 weeks after the end of treatment (after 8 weeks).

#### Method of measurement

According to National Cancer Institute-Common Terminology Criteria for Adverse Events (NCI-CTCAE)

### 2

#### Description

Severity of Neuropathy

#### Timepoint

Before and after treatment

#### Method of measurement

Nerve Conduction Study (NCS)

### 3

#### Description

Patient Overall Satisfaction with Treatment

#### Timepoint

At the end of treatment and after 4 weeks follow-up (after 8 weeks)

#### Method of measurement

Four-point Likert-type scale

### 4

#### Description

Safety Assessment

#### Timepoint

After each acupuncture session

#### Method of measurement

Signs and/or reports of excessive bruising, local persistent pain, and evidence of bleeding

### 5

#### Description

Adverse events

#### Timepoint

Any time in course of study

#### Method of measurement

Report by patients and researchers

## Intervention groups

### 1

#### Description

Intervention group: Acupuncture treatment will be implemented three times per week for four weeks. According to the literature reviews and clinical experiences of a responsible researcher, two groups of points will be used including local points and general points: Qihai (CV 6), Baihui (GV 20), Bilateral Zusanli (ST 36), Sanyinjiao (SP 6), Hegu (LI 4), Quchi (LI 11), Taichong (LR 3) as general points, and bilateral Bafeng (EX-LE 10) and Baxie (EX-UE 9) as local points. Patients with chemotherapy induced peripheral neuropathy (CIPN) symptoms in the lower extremities will be treated with only Bafeng, while patients with CIPN symptoms in the upper extremities will be treated with only Baxie. Patients with CIPN symptoms in both the upper and lower extremities will be treated with a combination of these two points. Additional individualized points will be used, if needed, according to patient symptoms, including Tianshu (ST 25), Waiguan (SJ 5) and Zhaohai (KI 6) for constipation, Neiguan (PC 6) and Zhongwan (CV 12) for vomiting, and Sishencong (EX-HN1) and Shenmen (HE 7) for insomnia. When applying general points, a reinforcing technique will be used at Qihai (CV 6), Zusanli (ST 36), Sanyinjiao (SP 6), and Baihui (GV 20), while a reducing technique will be applied at Hegu (LI 4) and Quchi (LI 11), and an even technique at Taichong (LR 3). For local points, only a reducing technique will be used. After using alcohol for local skin sterilization, disposable sterilized filiform needles (0.25×0.40 mm; Zhongyan Taihe, Beijing Zhongyan Taihe Medical Instruments center, Beijing, China) will be inserted perpendicularly at the depth of 10-15 mm in general points and 5-7 mm in local points, with proper needling manipulation to induce 'de qi' (the arrival of qi). After achieving de qi, the needles will be retained for 20 minutes.

#### Category

Treatment - Other

## 2

### Description

Control group: In this group, the treatment consist of one tablet of vitamin B1 300 mg (Jalinous and GNC pharmaceutical companies) and three capsules of gabapentin 300 mg (Abidi and Jiangsu Enhua pharmaceutical companies) per day for four weeks.

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Dongzhimen hospital

##### Full name of responsible person

Somayeh Iravani

##### Street address

Department of Hematology and Oncology, Dongcheng District

##### City

Beijing

##### Postal code

100700

##### Phone

+86 10 8401 3145

##### Email

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### 2

#### Recruitment center

##### Name of recruitment center

Imam Khomeini hospital

##### Full name of responsible person

Somayeh Iravani

##### Street address

Keshavarz boulevard, Bagherkhan street

##### City

Tehran

##### Province

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Beijing University of Chinese Medicine

##### Full name of responsible person

Baixiao Zhao

##### Street address

No.11, 3rd North Ring Road, Chaoyang District

##### City

Beijing

##### Postal code

100029

##### Phone

+86 10 5391 2012

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baixiao100@vip.sina.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Beijing University of Chinese Medicine

#### Proportion provided by this source

50

#### Public or private sector

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

*empty*

#### Country of origin

#### Type of organization providing the funding

Academic

### 2

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Mohammad Ali Sahraian

##### Street address

6th floor, Vice-Chancellor in Research Affairs-Tehran University of Medical Sciences, central building, Qods street, Keshavarz Blvd.

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#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Tehran University of Medical Sciences

#### Proportion provided by this source

50

#### Public or private sector

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

**Country of origin**

**Type of organization providing the funding**

Academic

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Beijing University of Chinese Medicine

**Full name of responsible person**

Somayeh Iravani

**Position**

PhD student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Acupuncture-moxibustion and tuina

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University of Chinese Medicine, No.11 North 3rd Ring  
East Road, Chaoyang District, Beijing 100029, China

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**Person responsible for scientific inquiries**

**Contact**

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**Full name of responsible person**

Amir Hooman Kazemi Motlagh

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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**Person responsible for updating data**

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**Name of organization / entity**

Beijing University of Chinese Medicine

**Full name of responsible person**

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**Position**

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**Latest degree**

Medical doctor

**Other areas of specialty/work**

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available