Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 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 ≥ 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

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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 ≥ 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

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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
Befor 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
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2

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
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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
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
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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

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Acupuncture-moxibustion and tuina

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Position

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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