Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Impact of topical garlic oil on chemotherapy-induced peripheral neuropathy

Protocol summary

Study aim
To evaluate and compare the effect of topical garlic oil on chemotherapy-induced peripheral neuropathy

Design
A double-blind, parallel-group randomized clinical trial of 66 patients, using block randomization.

Settings and conduct
This clinical trial will be conducted on 66 cancer patients experiencing neuropathy symptoms following chemotherapy, in the Radiation Therapy Department of Vasei Hospital, Sabzevar University of Medical Sciences. Participants will be randomly divided into two groups: the intervention group, receiving topical garlic oil, and the control group, receiving a placebo (paraffin). To ensure blinding of the participants, healthcare personnel and researcher, the garlic oil and placebo will be delivered in identical, coded packages. Pain intensity and patient performance will be assessed using the BPI-SF questionnaire, while neuropathy severity will be evaluated using the EORTC QLQ-CIPN20 standard questionnaire at baseline, at the end of each week and after 6 weeks.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Cancer patients with neuropathy, following chemotherapy, approved by the oncologist, and a pain score greater than 1 based on the McGill Pain Questionnaire-2 and the use of one of the chemotherapy regimens that cause neuropathy Exclusion criteria: Neuropathy with other causes; allergy to garlic oil or a placebo

Intervention groups
In the intervention group, 1 cc of garlic oil is applied to the soles of the feet and the backs of the hands and feet, from the wrist to the fingertips, twice daily for 6 weeks. The placebo group receives an identical treatment using the placebo.

Main outcome variables
Pain intensity and functional performance; neuropathy severity

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20240713062420N1**
Registration date: **2024-09-26, 1403/07/05**
Registration timing: **prospective**

Last update: **2024-09-26, 1403/07/05**
Update count: **0**

Registration date
2024-09-26, 1403/07/05

Registrant information
Name
Shamim Shahrestani
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-10-22, 1403/08/01
Expected recruitment end date
2024-10-31, 1403/08/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Impact of topical garlic oil on chemotherapy-induced peripheral neuropathy

Public title
Impact of garlic oil on chemotherapy-induced peripheral neuropathy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Cancer patients with neuropathy, following chemotherapy, approved by the oncologist, and a pain score greater than 1 based on the McGill Pain Questionnaire-2 (SF-MPQ-2). The use of one of the following chemotherapy regimens that cause neuropathy, including taxane group drugs in weekly, 2-week, or 3-week regimens, such as the AC-Taxol, TCH, TC, or TAC regimens.
Exclusion criteria:
Diagnosis of depression, peripheral vascular disease Use of other drugs effective in treating neuropathy, such as gabapentin, pregabalin, or duloxetine diabetes or alcohol abuse Pregnancy or breastfeeding Severe underlying condition Allergy to garlic oil or a placebo
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **66**
Randomization (investigator's opinion)
Randomized
Randomization description
Based on the specified inclusion criteria, we will perform sampling, followed by random assignment to control and intervention groups using block randomization(AABB, ABAB, ABBA, BABA, BAAB, BBAA) determined by rolling a die. To align the blocks with the numbers on the die, we assign codes 1 to 6 to each of these quaternary blocks. Code 1 corresponds to the AABB block, code 2 to the ABAB block, code 3 to the ABBA block, code 4 to the BABA block, code 5 to the BBAA block, and code 6 to the BAAB block. Since our research requires a sample size of 66 individuals, we will roll the die 17 times (4 * 17 = 68) to ensure that at least 66 samples are included. When matching the die's outcome to the code associated with the blocks, the letter 'A' designates samples placed in the intervention group, while the letter 'B' designates samples placed in the control group.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants, healthcare personnel and researcher are blinded to the garlic oil and placebo (paraffin). To maintain blinding, both the garlic oil and placebo (paraffin) will be provided in identical, coded packaging. It is important to note that the garlic oil closely resembles the paraffin placebo in terms of consistency, appearance, and even odor, as well as the packaging used.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Sabzevar University of Medical Sciences
Street address
Sabzevar University of Medical Sciences, Tohidshahr Blvd
City
Sabzevar
Province
Razavi Khorasan
Postal code
9618637548
Approval date
2024-05-07, 1403/02/18
Ethics committee reference number
IR.MEDSAB.REC.1403.009

Health conditions studied

1

Description of health condition studied
Cancer
ICD-10 code
C80.1
ICD-10 code description
Malignant (primary) neoplasm, unspecified

2

Description of health condition studied
Chemotherapy induced peripheral neuropathy (CIPN)
ICD-10 code
G62.0
ICD-10 code description
Drug-induced polyneuropathy

Primary outcomes

1

Description

Pain intensity

Timepoint

At baseline, at the end of each week and at the end of the sixth week

Method of measurement

Brief Pain Inventory - Short form (BPI-SF) questionnaire

2

Description

functional performance

Timepoint

At baseline, at the end of each week and at the end of the sixth week

Method of measurement

Brief Pain Inventory - Short form (BPI-SF) questionnaire

3

Description

neuropathy severity

Timepoint

At baseline, at the end of each week and at the end of the sixth week

Method of measurement

European Organization for Research and Treatment of Cancer Quality of Life Questionnaire—Chemotherapy-Induced Peripheral Neuropathy Module (EORTC QLQ-CIPN20) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, 1 cc of garlic oil is applied twice daily for 6 weeks to the soles of the feet and the backs of the hands and feet, from the wrists to the fingertips. The garlic oil is sourced from Toba Tala Sabz Pharmaceutical Company.

Category

Treatment - Drugs

2

Description

Control group: In the intervention group, 1 cc of garlic oil is applied twice daily for 6 weeks to the soles of the feet and the backs of the hands and feet, from the wrists to the fingertips.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Vasei hospital

Full name of responsible person

Dr. Fereshteh Ghorat

Street address

Vasei hospital., Tohid Shahr Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

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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

Sabzevar University of Medical Sciences

Proportion provided by this source

100

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
Sabzevar University of Medical Sciences

Full name of responsible person
Shamim Shahrestani

Position
Student

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
No more information

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

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not 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
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available