

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Evaluation of employing hypothermia for prevention of chemotherapy-induced peripheral neuropathy (CIPN)

Protocol summary

Study aim

Determining the effect of hypothermia on the frequency and severity of peripheral neuropathy caused by chemotherapy drugs

Design

A controlled, parallel-group, unblinded, randomized, phase 2 clinical trial of 60 patients. A table of random numbers will be used for randomization.

Settings and conduct

This study will be conducted in the Chemotherapy Center of Vasei Hospital in Sabzevar. Due to the nature of the study, it was not possible to blind the patients, the treating physician and the person investigating the evaluated outcomes to the group that the patient will be included in.

Participants/Inclusion and exclusion criteria

The study population includes breast cancer patients. Entry criteria included Consenting to use the cooling device and completing the consent form, using one of the chemotherapy regimens containing drugs associated with peripheral neuropathy, appropriate performance level, age greater than 18 years and less than 75 years, and exclusion criteria including a history of melanoma. He had a history of cryoglobulinemia, systemic lupus erythematosus, and poorly controlled diabetes. Also, patients will be excluded from the study if they do not tolerate hypothermia and withdraw their consent.

Intervention groups

In the intervention group, patients will use cold gloves and slippers during chemotherapy.

Main outcome variables

Using the European Organization for Research and Treatment of Cancer (EORTC) quality of life questionnaire (QLQ) chemotherapy induced peripheral neuropathy (CIPN) 20, the severity of neuropathy was measured at the beginning of the study (before the start of the intervention) and session 6 and 12 chemotherapy and 3 months after completion of treatment will be done.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231108059991N1**

Registration date: **2023-12-28, 1402/10/07**

Registration timing: **prospective**

Last update: **2023-12-28, 1402/10/07**

Update count: **0**

Registration date

2023-12-28, 1402/10/07

Registrant information

Name

Fateme Asadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 915 786 8871

Email address

fatemeasadi495@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-21, 1402/11/01

Expected recruitment end date

2024-09-22, 1403/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of employing hypothermia for prevention of chemotherapy-induced peripheral neuropathy (CIPN)	
Public title	Determining the effect of hypothermia in improving peripheral neuropathy caused by chemotherapy drugs
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Consent to use the cooling device and complete the consent form The use of one of the chemotherapy regimens with the occurrence of neuropathy including drugs from the taxanes Performance more than 70% Age less than 75 years Exclusion criteria: History of melanoma History of systemic lupus erythematosus Poor controlled diabetes Dissatisfaction with using the device History of cryoglobulinemia
Age	From 18 years old to 75 years old
Gender	Female
Phase	N/A
Groups that have been masked	No information
Sample size	Target sample size: 60
Randomization (investigator's opinion)	Randomized
Randomization description	According to the sample size of the present study, the random allocation of the intervention in two groups will be done with the permutation block method.
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics committee of Sabzevar University of Medical Sciences
Street address	Nuclear Martyrs Boulevard, above the Memorial of the Unknown Martyrs, Campus of the University of Medical Sciences, Vice Chancellor for Research and Technology
City	

Sabzevar	
Province	Razavi Khorasan
Postal code	9617913114
Approval date	2023-11-07, 1402/08/16
Ethics committee reference number	IR.MEDSAB.REC.1402.074
Health conditions studied	
<u>1</u>	
Description of health condition studied	chemotherapy induced neuropathy
ICD-10 code	G62.0
ICD-10 code description	Drug-induced polyneuropathy
Primary outcomes	
<u>1</u>	
Description	Severity of neuropathy
Timepoint	Measuring the severity of neuropathy at the beginning of the study (before the start of the intervention) and the 6th and 12th sessions of chemotherapy and 3 months after the end of the treatment.
Method of measurement	European Organisation for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire (QLQ) Chemotherapy-Induced Peripheral Neuropathy (CIPN) 20
<u>2</u>	
Description	Quality of Life
Timepoint	Measuring the severity of neuropathy at the beginning of the study (before the start of the intervention) and 3 months after the end of the treatment.
Method of measurement	World Health Organization Quality of Life Questionnaire
Secondary outcomes	empty
Intervention groups	
<u>1</u>	
Description	Intervention group: Patients in this group from the time of commencing chemotherapy (or simultaneously with premedication), during the time of receiving the chemotherapy and 15 minutes after it will use the foot wrap and hand wrap connected to the cooling unit for

both hands and/or feet. The device continuously maintains the surface temperature of hands and feet in the range of 3 to 5 degrees Celsius.

Category

Treatment - Devices

2

Description

Control group: Patients in this group will not use any foot wrap and hand wrap during chemotherapy.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Vasei Educational and Medical Center

Full name of responsible person

Seyed Alireza Javadinia

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Vasei hospital , Shohadaye Hasteii Blvd

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javadinia.alireza@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Kaze Hasanpour

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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

Seyed Alireza Javadinia

Position

Consultant

Latest degree

Specialist

Other areas of specialty/work

Radiotherapy

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Position

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Latest degree

Specialist

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Person responsible for updating data

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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

Not applicable

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