# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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)

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**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

### 1

**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

### 1

**Description of health condition studied**
chemotherapy induced neuropathy
**ICD-10 code**
G62.0
**ICD-10 code description**
Drug-induced polyneuropathy

## Primary outcomes

### 1

**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

### 2

**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

### 1

**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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drhassanpour@yahoo.com

**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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## Person responsible for scientific inquiries

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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