

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effects of Aromatherapy with Lavender and Peppermint Essential Oils on the symptoms of chemotherapy-induced peripheral neuropathy in patients with breast cancer

#### Protocol summary

##### Study aim

Investigating the effect of aromatherapy with lavender and peppermint essential oil on the symptoms of peripheral neuropathy caused by chemotherapy in patients with breast cancer

##### Design

Clinical trial with control group, with single group, non-blinded, randomized, phase 3 on 34 patients. To randomize from Excel software

##### Settings and conduct

Radio-oncology department of Shahada Tajrish Hospital  
Patients with breast cancer who have received chemotherapy with taxanes and have neuropathy complications will receive the drug, and the extent of their complications will be re-evaluated after the period of taking the drug

##### Participants/Inclusion and exclusion criteria

Breast cancer patients with a history of chemotherapy with "Taxanes" who ; have symptoms of peripheral neuropathy based on specialized neurological examination and diagnosis and meet the inclusion criteria

##### Intervention groups

The intervention group will receive lavender and peppermint essential oil and the control group will receive a placebo (base oil) should use it to the tip of the toes) and on the hands (from the wrist to the tips of the fingers) for a period of 4 weeks

##### Main outcome variables

The initial level of pain, numbness, movement disorder, symptoms of peripheral neuropathy, type of chemotherapy drug, dose of chemotherapy drug, dose of lavender and peppermint essence/placebo dose, rate of neuropathy complications after using the drug

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230407057835N1**

Registration date: **2023-06-26, 1402/04/05**

Registration timing: **prospective**

Last update: **2023-06-26, 1402/04/05**

Update count: **0**

##### Registration date

2023-06-26, 1402/04/05

##### Registrant information

##### Name

Omid Khaleghpanah

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 913 750 5303

##### Email address

omidkh21@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-07-23, 1402/05/01

##### Expected recruitment end date

2023-09-23, 1402/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Effects of Aromatherapy with Lavender and Peppermint Essential Oils on the symptoms of chemotherapy-induced peripheral neuropathy in patients with breast cancer

## Public title

Effects of Aromatherapy with Lavender and Peppermint Essential Oils on symptoms of chemotherapy-induced peripheral neuropathy

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

patient is undergoing chemotherapy or has a history of chemotherapy with "Taxanes" at most in the last 2 months Based on the expert's diagnosis, patient has grade B peripheral neuropathy caused by ;chemotherapy based on the PNQ questionnaire;

### Exclusion criteria:

## Age

From **18 years** old to **80 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **34**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Individual simple randomization by statistical software

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shahid Behesti University of medical sciences

##### Street address

Simaye Iran Ave, South Falamak and Zarafshan Blv, Qods Town

##### City

Tehran

##### Province

Tehran

##### Postal code

1985717443

## Approval date

2022-12-14, 1401/09/23

## Ethics committee reference number

IR.SBMU.MSP.REC.1401.458

## Health conditions studied

### 1

#### Description of health condition studied

Peripheral neuropathy caused by chemotherapy with "Taxane" drugs

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Peripheral neuropathy symptoms based on PNQ questionnaire

#### Timepoint

Measurement of peripheral neuropathy symptoms based on PNQ questionnaire 1 month after drug use

#### Method of measurement

PNQ questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Breast cancer patients with a history of chemotherapy with "Taxanes", who have symptoms of peripheral neuropathy based on neurological examination and diagnosis and meet the inclusion criteria, will receive lavender and peppermint essential oils. To the participants It is explained that the oil should be applied 2.5 cc in the morning and 2.5 cc at night before going to bed on the legs (from the ankles to the tips of the toes) and on the hands (from the wrists to the tips of the fingers) for a period of 4 weeks

#### Category

Rehabilitation

### 2

#### Description

Control group: Patients with breast cancer with a history of chemotherapy with "Taxanes", who have symptoms of peripheral neuropathy based on neurological examination and diagnosis and meet the criteria for entering the study, will receive the placebo. The participants will be explained. who should apply 2.5 cc of oil in the morning and 2.5 cc at night before going to bed on the legs (from the ankles to the tips of the toes) and

on the hands (from the wrists to the tips of the fingers)  
for a period of 4 weeks

**Category**

Placebo

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

radio-oncology department of Shohada Tajrish  
Hospital

**Full name of responsible person**

Mona Malekzadeh

**Street address**

Shahrdari Ave, Tajrish square

**City**

Tehran

**Province**

Tehran

**Postal code**

1989934148

**Phone**

+98 21 2271 8081

**Email**

omidkh21@gmail.com

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr. Babak Shokri

**Street address**

next to Taleghani hospital, Tabnak Ave, Evin,  
Chamran highway

**City**

Tehran

**Province**

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**Postal code**

1985717443

**Phone**

+98 21 2243 9783

**Email**

omidkh21@gmail.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Omid Khaleghpanah

**Position**

radio-oncology assistant

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Radiotherapy

**Street address**

No 24, Alizadeh Tabrizi Ave , north Zanjan street,  
Sattarkhan

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**Province**

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1455687464

**Phone**

+98 913 750 5303

**Email**

omidkh21@gmail.com

**Person responsible for scientific  
inquiries**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mona Malekzade

**Position**

radio-oncologist

**Latest degree**

Specialist

**Other areas of specialty/work**

Radiotherapy

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Shahrdari Ave, Tajrish square

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Omid Khaleghpanah

**Position**

radio-oncology assistant

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Radiotherapy

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**Postal code**

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**Email**

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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**

Difficulty in accessing patients due to their general condition and their low willingness

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

It will be mentioned in the text of the final thesis

**When the data will become available and for how long**

It will be mentioned in the text of the final thesis

**To whom data/document is available**

It will be mentioned in the text of the final thesis

**Under which criteria data/document could be used**

It will be mentioned in the text of the final thesis

**From where data/document is obtainable**

It will be mentioned in the text of the final thesis

**What processes are involved for a request to access data/document**

It will be mentioned in the text of the final thesis

**Comments**