Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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Iran (Islamic Republic of)
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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

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Shahrdari Ave, Tajrish square

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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

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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

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

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Person responsible for updating data

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Latest degree
Medical doctor

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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