Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of topical herbal oil based on lavender, Acorus calamus and Turmeric on Taxanes -induced peripheral neuropathy in cancer patients

Protocol summary

Study aim

The effect of topical herbal oil based on lavender, Acorus calamus and Turmeric on Taxanes - induced peripheral neuropathy in cancer patients and control group

Design

A controlled, double-blind, randomized, phase 2 clinical trial with parallel group, on 75 patients. The rand function of Excel software was used for randomization.

Settings and conduct

The location is the Radio-Oncology department of Mahdieh Hospital The control group received 1 cc of placebo oil three times a day, and the intervention group received 6 cc of herbal oil on the surface of the feet and hands. Drug; glass containers with a dropper of one shape and the name of the product as a code Duration of the intervention is 4 weeks, drug test 24 hours before use

Participants/Inclusion and exclusion criteria

A 4-week double-blind randomized clinical trial of 74 volunteer patients, 18-80 years of age, patients with breast, gynecological and urological cancer inTehran Mahdieh Hospital, with peripheral neuropathy, response to treatment, assessment of improvement in the scores of the NPS, the FACT/GOG-Ntx, PNQ scale by a physician

Intervention groups

Entry criteria • Having cancer with a pathological answer • undergoing chemotherapy or completed chemotherapy within the last two months • Patients with neuropathy, as determined by a neurologist, due to Taxanes chemotherapy • Having peripheral neuropathy of lower or upper limbs or both • Having at least Grade B neuropathy based on the PNQ questionnaire • Not having Guillain-Barre, diabetes, multiple sclerosis and carpal tunnel syndrome • Age 18 - 80 • Willingness to collaborate on the project • Insensitivity to herbal medicines • Stage 1 to 3 patients • No amputations or no wounds on hands and feet • Not having skin cancer • no concurrent radiotherapy

Main outcome variables

Sensory and motor disorders of upper and lower limbs, neuropathic pain, symptoms of neuropathy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240306061184N1**
Registration date: **2025-04-23, 1404/02/03**
Registration timing: **registered_while_recruiting**

Last update: **2025-04-23, 1404/02/03**
Update count: **0**

Registration date

2025-04-23, 1404/02/03

Registrant information

Name

Mehri Sadeghi Khansari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-07-22, 1403/05/01

Expected recruitment end date

2025-07-23, 1404/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of topical herbal oil based on lavender, Acorus calamus and Turmeric on Taxanes -induced peripheral neuropathy in cancer patients

Public title
The effect of topical herbal oil based on lavender, Acorus calamus and Turmeric on Taxanes -induced peripheral neuropathy in cancer

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with breast, gynecological and urology cancer in the age range of 18-80 years with complaints of peripheral neuropathy symptoms, according to the opinion of a neurologist; their neuropathy is due to chemotherapy with taxane drugs. Are undergoing chemotherapy or have a history of chemotherapy, provided that no more than two months have passed since the completion of their chemotherapy, regardless of the number of chemotherapy courses.

Exclusion criteria:
Having diabetes and other neuropathies such as Guillain-Barré, multiple sclerosis, and carpal tunnel syndrome Allergy to herbal medicines Stage 4 cancer patients Patients who perform radiotherapy at the same time as chemotherapy

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **74**
More than 1 sample in each individual
Number of samples in each individual: **37**
37 people in the intervention group (herbal oil based on lavender, Acorus calamus and Turmeric) and 37 people in the control group (baby oil)

Randomization (investigator's opinion)
Randomized

Randomization description
The participants are placed in two groups of test and control by block randomization method According to the sample size, we will have 9 blocks of 8 people and 1 block of 2 people. In each block, half of the lottery papers will correspond to "I" or intervention and the rest will be "p" or placebo. The medicine and placebo containers will be identical and they will be identified only based on a code that identifies which medicine and which is placebo.

Blinding (investigator's opinion)
Double blinded

Blinding description
The doctor and the patient are not aware of the type of treatment (placebo or herbal product) assigned either before or after the treatment. In other words, the patient does not know which group he will be placed in and does not know whether the drug he received is the main drug under study or not. On the other hand, the doctor examining the effect of the drug should not be aware of the type of intervention.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Mazandaran university of Medical Sciences

Street address
Traditional and Complementary Medicine Research Center, Khazar Blvd, Sari, Mazandaran

City
Sari

Province
Mazandaran

Postal code
4815733971

Approval date
2024-02-28, 1402/12/09

Ethics committee reference number
IR.MAZUMS.REC.1402.665

Health conditions studied

1

Description of health condition studied
Taxanes-induced peripheral neuropathy

ICD-10 code
G62.0

ICD-10 code description
Drug-induced polyneuropathy

Primary outcomes

1

Description
Sensory and motor disorders and pain and symptoms of neuropathy in the lower and upper limbs

Timepoint

The beginning of the study (before the start of the intervention) and 28 days after the start of topical herbal oil consumption (the end of the intervention)

Method of measurement

To quantitatively evaluate peripheral neuropathy before and after intervention(Questionnaire FACT/GOG-Ntx Version 4)Functional Assessment of Cancer Therapy for patients with neurotoxicity questionnaire - version 4 (FACT-GOG-NTX), Qualitative symptoms of peripheral neuropathy based on the scalePNQ (Patient Neurotoxicity Questionnaire), Pain before and after the intervention; Neuropathic Pain Scale (NPS)

Secondary outcomes

1

Description

Registration of possible complications

Timepoint

While studying

Method of measurement

Side effects registration form

Intervention groups

1

Description

Intervention group: In the test group, the participants are asked to apply 1 cc of oil (vegetable) on the surface of the foot (from the ankle to the tip of the toes) and the surface of the hand (from the wrist to the tip of the fingers) three times a day. spread, a total of 6 cc daily.

Category

Treatment - Drugs

2

Description

Control group: In the control group, the participants are asked to apply 1 cc of oil (placebo) on the surface of the foot (from the ankle to the tip of the toes) and the surface of the hand (from the wrist to the tip of the fingers) three times a day. spread, a total of 6 cc daily.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Radiotherapy-Oncology, Mahdieh Hospital (Tehran)

Full name of responsible person

Masoumeh Keshvari

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Department of Radiotherapy-Oncology, Mahdieh Hospital, Rajab Niya St, Shush Square, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Vice President of Research and Technology of Mazandaran University of Medical Sciences

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Traditional and Complementary Medicine Research Center, Khazar Blvd, next to Baghban Medical Complex (Toubi), Sari, Mazandaran

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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

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Mohammad Yosofpoor

Position

Associate professor

Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Undecided - It is not yet known if there will be a plan to make this available
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
Title and more details about the data/document
Information on the main outcome and secondary outcome
When the data will become available and for how long
6 months after the publication of the results
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
For research purposes
From where data/document is obtainable
dr.msadeghi4431@gmail.com Dr. Mehri Sadeghi Khansari
What processes are involved for a request to access data/document
A maximum time is one month
Comments