

# 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 randomization function of Excel software was used for randomization.

##### Settings and conduct

The location is the Radio-Oncology department of Mahdiah 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 in Tehran Mahdiah 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)

##### Phone

+98 21 7782 4506

##### Email address

dr.msadeghi4431@gmail.com

##### 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 scale PNQ (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, Mahdiah Hospital (Tehran)

##### **Full name of responsible person**

Masoumeh Keshvari

##### **Street address**

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

##### **City**

Tehran

##### **Province**

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##### **Postal code**

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##### **Phone**

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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

##### **Street address**

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

##### **City**

Sari

##### **Province**

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##### **Postal code**

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##### **Phone**

+98 11 3324 4893

##### **Email**

tcmrcmazums@gmail.com

#### **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**

Traditional Medicine

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

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Medical doctor

**Other areas of specialty/work**

Traditional Medicine

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**Person responsible for scientific 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**

Traditional Medicine

**Street address**

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**Phone**

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**Email**

m.yousefpour@mazums.ac.ir

**Person responsible for updating data****Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Mehri Sadeghi Khansari

**Position**

PhD student of Iranian Persian Medicine

**Latest degree****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**