

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of the efficacy of Trachyspermum ammi topical cream on taxane induced peripheral neuropathy symptoms in cancer patients : a pilot study

#### Protocol summary

##### Study aim

Evaluation of the effectiveness of topical cream on the symptoms of peripheral neuropathy caused by chemotherapy with taxanes in cancer patients

##### Design

a parallel-group randomized clinical trial, Double-blinded

##### Settings and conduct

Forty patients with cancer, undergoing or have a history of chemotherapy with taxanes, were randomly diagnosed with peripheral neuropathy symptoms and inclusion criteria. There are two groups of drugs and placebo. Patients apply topical cream twice a day (morning and night) on all four lower and upper limbs, from the ankle to the toes, and from the wrist to the fingertips.

##### Participants/Inclusion and exclusion criteria

inclusion: Patients with cancer Patients whose neuropathy is due to chemotherapy with taxane drugs or a history of chemotherapy taxane that is a maximum of two months from completion of chemotherapy last Having symptoms of peripheral neuropathy Neuropathy is based on the diagnosis of a neurologist due to chemotherapy Aged between 18 and 80 years Willingness to collaborate in the study exclusion: diabetes Carpal tunnel syndrome Reluctance to stay in the study Acute psychological symptoms such as depression (taking medication for it) Unforeseen treatments such as surgery, radiation therapy, or immunotherapy that were not previously part of the participant's treatment plan Vitamin B6 deficiency or high (diagnosed by doctor and interview) Any signs of allergy or side effects from the drug Deterioration of the patient Renal failure Brain metastasis History of the axilla or lumbar or pelvic radiotherapy A history of neuropathy due to other conditions that the person had before starting chemotherapy or getting cancer

##### Intervention groups

There are two intervention groups in this study, one

group gets a Trachyspermum Ammi topical cream, and the other group receives the placebo ointment

##### Main outcome variables

pain tingling:symptoms of peripheral neuropathy

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20131218015860N6**

Registration date: **2021-07-06, 1400/04/15**

Registration timing: **prospective**

Last update: **2021-07-06, 1400/04/15**

Update count: **0**

##### Registration date

2021-07-06, 1400/04/15

##### Registrant information

##### Name

Ghazaleh Heydarirad

##### Name of organization / entity

School of Traditional Medicine, Traditional Medicine and Materia Medica Research Center, Shahid Beheshti

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8877 6027

##### Email address

dr.ghazalrad@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-08-23, 1400/06/01

##### Expected recruitment end date

2022-02-20, 1400/12/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of the efficacy of Trachyspermum ammi topical cream on taxane induced peripheral neuropathy symptoms in cancer patients : a pilot study

**Public title**

Evaluation of the efficacy of Trachyspermum ammi topical cream on neuropathy symptoms in cancer patients

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Patients with cancer Patients whose neuropathy is due to chemotherapy with taxane drugs or a history of chemotherapy taxane that is a maximum of two months from completion of chemotherapy last Having symptoms of peripheral neuropathy Neuropathy is based on the diagnosis of a neurologist due to chemotherapy Aged between 18 and 80 years Willingness to collaborate in the study

**Exclusion criteria:**

diabetes Carpal tunnel syndrome Reluctance to stay in study Acute psychological symptoms such as depression (taking medication for it) Unforeseen treatments such as surgery, radiation therapy or immunotherapy that were not previously part of the participant's treatment plan Vitamin B6 deficiency or high (diagnosed by doctor and interview) Any signs of allergy or side effects from the drug Deterioration of the patient renal failure Brain metastasis Previous history of axilla or lumbar or pelvic radiotherapy A history of neuropathy due to other conditions that the person had before starting chemotherapy or getting cancer

**Age**

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

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, the Restricted Randomization method of block randomization is used. Blocking is used to balance the number of samples assigned to each of the study groups. The randomization method will be balanced

using block randomization and will be done in 4 blocks using a computer. Each drug is named with a number from 1 to 40. Patients are divided into two groups for the trial: the first and group (20 people) groups or drug groups and the second control group (20 people) placebo group. Both groups are equally divided in terms of characteristics and conditions. The control group is assigned to "A" and the intervention group to "B," and then these two groups are divided into 6 blocks of 4: (1)AABB, (2) BBAA, (3) ABAB, (4) B A B A, (5) A B B A, (6) BAAB. These blocks are randomly stacked together by a computer to form a chain of random groups (e.g., BBAA AABB ABAB BABA ABBA BAAB). Patients then enter these groups in the order of enrollment. For randomization, a randomization software for random sequence software called Random allocation software is used. In addition to simple randomization, this software can generate random sequences by block generation method. For concealment, we use allocation concealment, which is the method used to execute a random sequence on the study participants. The assigned group is not known before the individual is assigned. Using opaque envelopes sealed with random sequences (Sequentially numbered, sealed, opaque envelopes) in which in this method each random sequence is recorded on a card and the cards are in the envelopes respectively. Are placed. To maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants into the study, one of the envelopes of the letter is opened in order, and the assigned group of the participant is revealed.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Trachyspermum ammi topical cream and placebo was coded, patient and researcher were blind

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics Committee on Biomedical Research of Shahid Beheshti University of Medical sciences

**Street address**

Shahid Beheshti University of Medical sciences, Daneshju Blv.

**City**

Tehran

**Province**

Tehran

**Postal code**

1983963113

**Approval date**

2021-03-09, 1399/12/19

**Ethics committee reference number**

IR.SBMU.RETECH.REC.1399.1354

**Health conditions studied****1****Description of health condition studied**

Neoplastic (malignant) related neuropathy

**ICD-10 code**

G62.0

**ICD-10 code description**

Drug-induced polyneuropathy

**Primary outcomes****1****Description**

pain

**Timepoint**

Weeks zero and four

**Method of measurement**

Visual Analogue Scale

**2****Description**

tingling

**Timepoint**

Weeks zero and four

**Method of measurement**

Visual Analogue Scale

**3****Description**

symptoms of peripheral neuropathy

**Timepoint**

Weeks zero and four

**Method of measurement**Chemotherapy Induced Peripheral Neuropathy  
Assessment Tool (CIPNAT) questionnaire**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: Trachyspermum Ammi and almond oil in a cream formulation at a rate of 5% of the total cream will be used. Trachyspermum Ammi essential oil

(10% of the total cream) will be added to the cream. The cream was filled in white sealed multilayer tubes. Before the clinical trial, cream samples were evaluated pharmacologically (viscosity test, pH assessment, and microbial limit test). The content of thymol, Trachyspermum Ammi cream was standard ( $02/0 \pm 34/2$  g per 50 g of cream). . Both creams are white. Cancer patients with taxane-induced neuropathy receive 1 mg of Trachyspermum Ammi topical cream twice a day for four weeks.

**Category**

Treatment - Drugs

**2****Description**

Control group: In the placebo formulation, almond oil will be used at the rate of 5% of the total cream (equal to the amount of Trachyspermum Ammi cream) and paraffin oil (10% of the whole cream). The cream was filled in white sealed multi-layered tubes. To create the aroma of placebo cream with Trachyspermum Ammi cream, the inside of the tubes was washed with Trachyspermum Ammi distilled water, before being filled with placebo cream; both creams are white. Cancer patients with taxane-induced peripheral neuropathy, receiving ointment of placebo, 1 mg twice a day for four weeks.

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Shohadaye Tajrish Hospital

**Full name of responsible person**

Dr. Ghazaleh Heydarirad

**Street address**

Shohadaye Tajrish Hospital, Tajrish Sq., Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1989934148

**Phone**

+98 21 25719

**Email**

pr\_shohada@sbm.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Rasool Choopani

**Street address**

No. 19, Shahid Abbaspour Bridge (Tavanir), Vali Asr Ave. Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1516745811

**Phone**

+98 21 8877 3521

**Email**

rasoolchoopani@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**

Ghazaleh Heydarirad M.D

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Traditional Medicine

**Street address**

No.8 Shams Alley, Opposite Sttree Tavanir, Vali Asr Street, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1516745811

**Phone**

+98 218877352

**Fax**

**Email**

dr.ghazalrad@sbmu.ac.ir

**Web page address**

<http://traditional.sbmu.ac.ir>

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Ghazaleh Heydarirad

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Traditional Medicine

**Street address**

No.8 Shams Alley, opposite St tavanir, Vali Asr Street, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1516745811

**Phone**

+98 21 8877 6027

**Fax**

+98 21 8877 6027

**Email**

dr.ghazalrad@sbmu.ac.ir

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Ghazaleh Heydarirad

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Traditional Medicine

**Street address**

No.8 Shams Alley, opposite St tavanir, Vali Asr Street, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1516745811

**Phone**

+98 21 8877 6027

**Fax**

+98 21 8877 6027

**Email**

dr.ghazalrad@sbmu.ac.ir

**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**

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