Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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
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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 ± 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Email
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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
Ghazaleh Heydarirad M.D

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Traditional Medicine

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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