

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### Evaluation of topical *Costus sp.* preparation efficacy in treatment of taxane induced peripheral neuropathy in cancer patients : a pilot study and a randomised controlled trial

#### Protocol summary

##### Study aim

Evaluation effects of topical *Costus sp.* preparation on taxane induced peripheral neuropathy in cancer patients

##### Design

Two arm parallel group randomized clinical trial, Double-blinded

##### Settings and conduct

50 cancer patients 18 to 80-year-old who have taxane induced peripheral neuropathy, that are undergoing chemotherapy or at least two months after chemotherapy will enter the study, if a neurologist discovers that their neuropathy is due to chemotherapy with taxanes. Regardless of the number of chemotherapy courses, based on entry criteria, they will be entered in the study. Patients will be divided into two groups by simple random method. Group (A) will receive drug (*Costus sp.* ointment), Group (B) will receive placebo (placebo ointment).

##### Participants/Inclusion and exclusion criteria

Entry requirements: Cancer patients Patients undergoing chemotherapy or complete chemotherapy in the last two months Patients with complained of neuropathy whose neuropathy is due to chemotherapy with taxane drugs Having symptoms of peripheral neuropathy in all four organs Having at least B grade based on the PNQ questionnaire Having at least 18 years and maximum 80 years Conditions of failure to enter: Diabetes Renal failure Brain metastasis Having carpal tunnel syndrome

##### Intervention groups

There are two intervention groups in this study, one group gets a topical *Costus sp.* ointment, and the other group receives the placebo ointment

##### Main outcome variables

Chemotherapy Induced Peripheral Neuropathy score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20131218015860N5**

Registration date: **2019-03-10, 1397/12/19**

Registration timing: **retrospective**

Last update: **2019-03-10, 1397/12/19**

Update count: **0**

##### Registration date

2019-03-10, 1397/12/19

##### 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

2017-11-22, 1396/09/01

##### Expected recruitment end date

2018-07-21, 1397/04/30

##### Actual recruitment start date

2018-04-21, 1397/02/01

##### Actual recruitment end date

2018-12-21, 1397/09/30

**Trial completion date**

2020-02-19, 1398/11/30

**Scientific title**

Evaluation of topical Costus sp. preparation efficacy in treatment of taxane induced peripheral neuropathy in cancer patients : a pilot study and a randomised controlled trial

**Public title**

Evaluation of topical Costus sp. preparation efficacy in treatment of neuropathy in cancer patients

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients with cancer Patients undergoing chemotherapy or Complete chemotherapy in the last two months Patients with complained of neuropathy whose neuropathy is due to chemotherapy with taxane drugs Having symptoms of peripheral neuropathy in all four organs Having at least B grade based on the PNQ questionnaire Having at least 18 years and maximum 80 years

**Exclusion criteria:**

diabetes renal failure Brain metastasis Carpal tunnel syndrome

**Age**

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

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **50**

Actual sample size reached: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

simple randomization: The numbers from 1 to 50 is written on 50 papers and placed inside a bag. Each time a patient enters the study according to entry criteria, a paper is removed from the bag and the number that is written on the paper will be the number of intervention medication (which can be a Costus sp ointment or placebo).

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Costus sp 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**

2018-01-07, 1396/10/17

**Ethics committee reference number**

IR.SBMU.RETECH.REC.1396.842

**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**

Severity of neuropathy based on patient's statements

**Timepoint**

14, 21 and 28 days after interference

**Method of measurement**

Neuropathy Severity Scale questionnaire

**Secondary outcomes****1****Description**

Score of "The Cancer Neuropathy Scale"

**Timepoint**

The weeks of 0 and 4 after treatment

**Method of measurement**

The Cancer neuropathy Scale questionnaire

## Intervention groups

### 1

#### Description

Intervention group: cancer patients with taxane induced peripheral neuropathy, receiving ointment of Coctus sp, 1 mg three times daily for four weeks

#### Category

Treatment - Drugs

### 2

#### Description

Control group: cancer patients with taxane induced peripheral neuropathy, receiving ointment of placebo, 1 mg three times daily for four weeks

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Hossein hospital

##### Full name of responsible person

Dr. Ghazaleh Heydarirad

##### Street address

Imam Hossein hospital - Madani st - Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1617763141

##### Phone

+98 21 7343 2338

##### Fax

##### Email

info.rhmc@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Dr.Somayeh Esmaeili

##### Street address

Shams Alley, Vali-e-Asr Street, Shahid Beheshti University of Medical Sciences

##### City

Tehran

##### Province

Tehran

##### Postal code

1516745811

##### Phone

+98 21 8877 3521

##### Email

sesmaeili@sbmu.ac.ir

##### Grant name

Research Assistant of Shahid Beheshti University of Medical Sciences

##### 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

Dr. Ghazaleh Heydarirad

##### Position

Assistant Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Traditional Medicine

##### Street address

Shams Alley, Vali-e-Asr Street, Shahid Beheshti University of Medical Sciences

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##### Email

ghazalrad@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Dr. Ghazaleh Heydarirad

##### Position

Assistant Professor

##### Latest degree

Ph.D.

**Other areas of specialty/work**

Traditional Medicine

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr. Ghazaleh Heydarirad

**Position**

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**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**

Demographic data and the result of the clinical trial

**When the data will become available and for how long**

6 month later

**To whom data/document is available**

Researchers

**Under which criteria data/document could be used**

After publication of the extracted article of the clinical trial

**From where data/document is obtainable**

Sending Email to the researchers

**What processes are involved for a request to access data/document**

Sending the request via the email

**Comments**