

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 Behe

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

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1617763141

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Fax

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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

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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

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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