Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 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 Behe

Country

Iran (Islamic Republic of)

Phone

+98 21 8877 6027

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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 wirtten 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
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Imam Hossein hospital - Madani st - Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr.Somayeh Esmaeili
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Shams Alley, Vali-e-Asr Street, Shahid Beheshti University of Medical Sciences
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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
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Position
Assistant Professor
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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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