

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of topical *Citrullus colocynthis* fruit oil efficacy in treatment of chemotherapy-induced peripheral neuropathy in cancer patients

Protocol summary

Study aim

Determination of the efficacy of topical product *Citrullus colocynthis* fruit oil on the symptoms of peripheral neuropathy due to chemotherapy in cancer patients

Design

Two arm parallel group randomised clinical trial, doable blinded

Settings and conduct

Design of the study: Patients with cancer referring to Shahid Modarres Hospital of Tehran who have symptoms of chemotherapy-induced peripheral neuropathy. In order to blind the investigator, medications are named as "A" for *Citrullus colocynthis* oil and B for placebo. The patient don't aware of the type of drug he/she is assigned to. In addition, the groups are entered into statistical analysis as "A" and "B".

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Patients with cancer who have symptoms of peripheral neuropathy 2. The time period between patient's visit for enrolling to the study and the last time receiving chemotherapy is maximum two months 3. A neurologist recognizes that patient's neuropathy is due to chemotherapy 4. Age between 18-80 years old Exclusion criteria: 1. Patients with diabetes mellitus 2. Patients with brain metastasis 3. Patients with carpal tunnel syndrome 4. Unwillingness to participate in the study 5. Emerging acute psychological symptoms such as depression (and taking medication) 6. Deficiency or high levels of vitamin B6 (according to the doctor's interview and examination) 7. Any positive history of allergic reaction or complications due to *Citrullus colocynthis* 8. Patients with serious illness

Intervention groups

Group A: Use of topical product of *Citrullus colocynthis* fruit oil twice daily in upper and lower extremities Group B: Use of Placebo (fluid paraffin) twice daily in the upper and lower extremities

Main outcome variables

1. Chemotherapy Induced Peripheral Neuropathy score 2.

Symptoms and concerns associated specifically with chemotherapy-induced neuropathy score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150825023753N5**

Registration date: **2018-02-16, 1396/11/27**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-16, 1396/11/27**

Update count: **0**

Registration date

2018-02-16, 1396/11/27

Registrant information

Name

Mohammad Mahdi Parvizi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 71 3212 5592

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2018-03-16, 1396/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of topical Citrullus colocynthis fruit oil efficacy in treatment of chemotherapy-induced peripheral neuropathy in cancer patients

Public title

Effect of Citrullus colocynthis on neurological symptoms caused by cancer

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with cancer who have symptoms of peripheral neuropathy The duration between the patient's visit for enrolling to the study and the last time receiving chemotherapy is at most two month A neurologist will recognize that their neuropathy is due to chemotherapy Age between 18-80 years old

Exclusion criteria:

Patients with diabetes mellitus Patients with brain metastasis Patients with carpal tunnel syndrome Unwilling to participate in the study Creating acute psychological symptoms such as depression (such as taking medication) Deficiency or high levels of vitamin B6 (according to your doctor's interview and examination) Any positive history of allergic reaction or complications due to using Citrullus colocynthis Patients with serious illness

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation software Ink was used to create a randomization table

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to blind the investigator, medications (extracts) were named A (Citrullus colocynthis oil) and B (Placebo). The patient was not aware of the type of drug he was assigned to. The groups were also coded A and B to the statistical analyzer.

Placebo

Used

Assignment

Parallel

Other design features

Patients who is known case of cancer and has neurological complications due to chemotherapy and is in the range of 18 to 80 years old and has all the conditions for entry into the study.

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

2017-10-22, 1396/07/30

Ethics committee reference number

IR.SBMU.RETECH.REC.1396.448

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

Chemotherapy-induced peripheral neuropathy

ICD-10 code

G62.0

ICD-10 code description

Drug-induced polyneuropathy

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

Chemotherapy Induced Peripheral Neuropathy score

Timepoint

Before and after

Method of measurement

Using of Chemotherapy Induced Peripheral Neuropathy Assessment Tool (CIPNAT)

2**Description**

Symptoms and concerns associated specifically with chemotherapy-induced neuropathy score

Timepoint

Before and after

Method of measurement

Using Functional Assessment of Cancer
Therapy/Gynecologic Oncology Group-Neurotoxicity
(Fact/GOG-Ntx) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Topical use of Citrullus colocynthis fruit oil product, twice daily (morning and night), all four lower and upper extremities, from ankle to toe, and from wrist to fingertips, 1 cc for each limb group of patients for 1 month

Category

Treatment - Drugs

2

Description

Control group: Topical use of placebo (liquid paraffin) , twice daily (morning and night), all four lower and upper extremities, from ankle to toe, and from wrist to fingertips, 1 cc for each limb group of patients for 1 month.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Modarres Hospital, Tehran

Full name of responsible person

Dr. Nematollah Rostami

Street address

Shahid Modarres Hospital, Saadat Abad Ave

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Sponsors / Funding sources

1

Sponsor

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Grant name

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

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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