Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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Iran (Islamic Republic of)

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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 uising 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 lnk 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
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Sponsors / Funding sources

1

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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
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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