Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A randomized clinical trial of topical effect of Nigella sativa oil, on the symptoms of peripheral neuropathy induced by chemotherapy in cancer patients

Protocol summary

Summary

The objective of this trial was to evaluate the effect of Nigella sativa oil to improve symptoms caused by chemotherapy in patients with cancer. For this purpose, 70 cancer patients older than 16 years that In the last 6 months have been undergoing chemotherapy with neuropathic symptoms Placed on trial, Assuming that patients are without diabetes. This patient devided in 2 groups. In a group of drugs prescribed by Nigella sativa oil and paraffin oil as a placebo group given. Patients should oil twice daily topical over the wrist or leg down and gently massage the treated. Each of the patients who are treated unforeseen or worsening of the disease have been excluded, And severity of symptoms and quality assessment questionnaire and a 6-week observation period specified, Refer patients every two weeks and completed the questionnaires filled. At the end of treatment in terms of changes in sensorimotor collected and examined.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014092419182N1**
Registration date: **2015-02-23, 1393/12/04**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-02-23, 1393/12/04

Registrant information

Name

Mehdi Fallah

Name of organization / entity

School of Traditional Medicine, Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8877 3521

Email address

dr_fallah@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2013-12-22, 1392/10/01

Expected recruitment end date

2013-12-22, 1392/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A randomized clinical trial of topical effect of Nigella sativa oil, on the symptoms of peripheral neuropathy induced by chemotherapy in cancer patients

Public title

Effect of Nigella sativa oil on chemotherapy-induced neuropathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: the risk of cancer; chemotherapy in the last 3 months ; the signs of peripheral neuropathy ; non-diabetes ; Minimum age 16 years , a willingness to cooperate in the design ; Psychological and mental

health. Exclusion Criteria: unwillingness to continue the study; acute psychological symptoms such as depression, Unforeseen treatment such as radiotherapy ; signs of autonomic nervous system dysfunction ; any signs or symptoms of allergy caused by medication ; the patients' illness

Age
From **16 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee martyr Beheshti University of Medical Sciences

Street address
Vali Asr Ave. against tavanir Alley Shams

City
Tehran

Postal code

Approval date
2013-12-29, 1392/10/08

Ethics committee reference number
400/6408

Health conditions studied

1

Description of health condition studied
Chemotherapy-induced neuropathy

ICD-10 code
G62.2

ICD-10 code description
Polyneuropathy due to other toxic agents

Primary outcomes

1

Description
Symptoms of neuropathy

Timepoint
Weeks of the second, fourth and sixth from baseline

Method of measurement
Questionnaire

Secondary outcomes

1

Description
skin allergy

Timepoint
Second, fourth and sixth weeks of baseline

Method of measurement
questionnaire

Intervention groups

1

Description
Nigella sativa oil is used topically on the affected limb twice a day for 6 weeks

Category
Treatment - Drugs

2

Description
The use of paraffin oil as a placebo twice daily for 6 weeks

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Department Of Oncology, Shohada Hospital

Full name of responsible person
Mehdi Fallah

Street address
Tajrish Square, Valiasr St

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
School of Traditional Medicine, Traditional Medicine

and Materia Medica Research Center,Shahid Behes

Full name of responsible person

Rasool Choopani M.D, Ph.D, Assistant Professor

Street address

No.8 Shams Alley, opposite St tavanir, Vali Asr Street, Tehran

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

School of Traditional Medicine, Traditional Medicine and Materia Medica Research Center,Shahid Behes

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

School of Traditional Medicine Traditional Medicine and Materia Medica Research Center Shahid Behesh

Full name of responsible person

Dr. Mehdi Fallah

Position

PHD Assistant traditional medicine

Other areas of specialty/work

Street address

No.8 Shams Alley, Vali Asr Street, Tehran

City

Tehran

Postal code

Phone

+98 21 8877 6029

Fax

Email

dr_fallah@sbmu.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

School of Traditional Medicine Traditional Medicine and Materia Medica Research Center Shahid Behesh

Full name of responsible person

Dr. Mehdi Fallah

Position

ph.D student ofTraditional Medicine

Other areas of specialty/work

Street address

No.8 Shams Alley, Vali Asr Street, Tehran

City

Teran

Postal code

Phone

+98 21 8877 6029

Fax

Email

dr_fallah@sbmu.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

School of Traditional Medicine Traditional Medicine and Materia Medica Research Center Shahid Behesh

Full name of responsible person

Mehdi Fallah

Position

ph.D student ofTraditional Medicine

Other areas of specialty/work

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No.8 Shams Alley, Vali Asr Street

City

Tehran

Postal code

Phone

+98 21 8877 3521

Fax

+98 21 8877 6027

Email

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty