Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the efficacy and side effects of Black seed Oil in the treatment of peripheral neuropathy caused by oxaliplatin; a randomized, double-blind, placebo-controlled clinical trial

Protocol summary

Study aim

Evaluation of the efficacy and side effects of Black seed Oil in the treatment of peripheral neuropathy caused by oxaliplatin

Design

A Clinical trial with two parallel groups, with a control group, with placebo, double-blind, phase 3, with a sample size of 56 people. Randomization with the help of Excel software and quadruple blocks.

Settings and conduct

In order to investigate the therapeutic effect of black seed oil in peripheral neuropathy caused by oxaliplatin, which is performed at Imam Khomeini Hospital in Sari. This study has two arms, drug and placebo, and a four-digit code is assigned to each patient through the Excel program.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with chemotherapy-induced peripheral neuropathy (CIPN) grade 2 and 3 according to NCI CTCAE v5.0 criteria and patients over 18 years of age will be included in the study. Exclusion criteria: Patients with previous history of neurological diseases, neuropathic pains, severe liver failure, heavy alcohol users, simultaneous use of vitamin B1, B6 and B12 and supplements containing calcium and magnesium during the previous two weeks, Taking medications related to peripheral neuropathy such as gabapentin, pregabalin, venlafaxine, using topical analgesic products, history of diabetes, pregnant and lactating.

Intervention groups

Intervention group: black seed oil capsule 1000 mg, once a day for the first week and then twice a day for 7 weeks (8 weeks in total) along with duloxetine placebo. Control group: duloxetine 30 mg capsules, once daily for the first week and then twice for 7 weeks (8 weeks in total) along with black seed oil placebo.

Main outcome variables

severity of peripheral neuropathy; pain intensity; Quality of Life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090613002027N24**
Registration date: **2025-04-20, 1404/01/31**
Registration timing: **prospective**

Last update: **2025-04-20, 1404/01/31**
Update count: **0**

Registration date

2025-04-20, 1404/01/31

Registrant information

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Ebrahim Salehifar
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Mazandaran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-10, 1404/02/20

Expected recruitment end date

2026-03-20, 1404/12/29

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the efficacy and side effects of Black seed Oil in the treatment of peripheral neuropathy caused by oxaliplatin; a randomized, double-blind, placebo-controlled clinical trial

Public title
The effect of Black seed oil on oxaliplatin neuropathy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
People over the age of 18 Patients with chemotherapy-induced peripheral neuropathy (CIPN) grade 2 and 3 according to NCI CTCAE v5.0 criteria
Exclusion criteria:
Patients with previous history of neurological diseases such as hereditary and acquired neuropathies Patients with neuropathic pain due to conditions such as postherpetic neuralgia, uncontrolled diabetes with neuropathy, trigeminal neuralgia, spinal cord injury or other neurological diseases, known vitamin B12 deficiency, amyloidosis, neuromuscular diseases and connective tissue diseases Severe liver failure (liver enzymes more than three times the normal limit) History of diabetes History of alcohol consumption Simultaneous use of vitamins B1, B6 and B12 and supplements containing calcium and magnesium during the previous two weeks Taking medications related to peripheral neuropathy, such as gabapentin, pregabalin, venlafaxine Use of topical analgesic products Taking antiepileptic drugs Pregnant or lactating women Lack of consent to participate in the study
Age
From **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **56**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization process for assigning participants to receive either black seed oil or duloxetine will be conducted using Block Balanced Randomization (BBR). To ensure allocation concealment, a four-digit random number will be generated using a random number table to serve as each participant’s unique identification code, keeping the group assignment (A or B) concealed. Participants will be randomized in blocks of four into two groups: "black seed oil and duloxetine placebo" and "duloxetine and black seed oil placebo". Only the primary investigator will have access to the block information and the unique codes assigned to each participant. The medication and corresponding placebo will be pre-packaged according to the assigned codes and distributed to participants based on the randomization results. Arrangements will be made to ensure that patients receive Barij black seed oil and duloxetine manufactured by Abidi Pharmaceutical Company.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study will be conducted in a double-blind manner, meaning that the patient, the physician, and the clinical evaluator will all be unaware of the intervention received (either black seed oil or duloxetine). The medications and placebos will be prepared by a pharmaceutical company and provided to the patients in identical packaging labeled with the four-digit code.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Mazandaran Medical University
Street address
Faculty of Pharmacy, Payambar Azam Complex, 18 Km Farah Abad Blvd, Khazar Square, Sari, Mazandaran Province
City
Sari
Province
Mazandaran
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4815733971
Approval date
2025-04-06, 1404/01/17
Ethics committee reference number
IR.MAZUMS.REC.1404.029

Health conditions studied

1

Description of health condition studied
Peripheral neuropathy
ICD-10 code
G63

ICD-10 code description
Polyneuropathy in diseases classified elsewhere

Primary outcomes

1

Description
Severity of neuropathy
Timepoint
at baseline and week 2, week 4 and the end of week 8 after taking the drug
Method of measurement
Based on NCI CTCAE version 5, FACT/GOG-Ntx, Neuropathy pain scale, Patient Neurotoxicity Questionnaire

2

Description
intensity of pain
Timepoint
at baseline and week 2, week 4 and the end of week 8 after taking the drug
Method of measurement
based on Numeric pain rating scale

Secondary outcomes

1

Description
quality of life
Timepoint
at baseline and the end of week 8 after taking the drug
Method of measurement
based on EORTC QLQ-C30 version 3

Intervention groups

1

Description
Intervention group: Black seed oil capsule 1000 mg, daily for the first week and then twice a day for 7 weeks (8 weeks in total) along with duloxetine placebo.
Category
Treatment - Drugs

2

Description
Control group: Duloxetine 30 mg capsules, daily for the first week and then twice a day for 7 weeks (8 weeks in total) along with black seed oil placebo.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital, Sari
Full name of responsible person
Ebrahim Salehifar
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Ahmad Ali Enayati
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Moallem sq, Research and Technology Department of Mazandaran University of Medical Sciences
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran 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
Mazandaran University of Medical Sciences

Full name of responsible person
Ebrahim salehifar

Position
Professor

Latest degree
Specialist

Other areas of specialty/work
clinical pharmacy

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
there is no plan for publishing the protocol of study because it is accessible in IRCT

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not 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
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
All data are shareable after publishing

When the data will become available and for how long
Start the access period 6 months after publishing the result

To whom data/document is available
All researchers

Under which criteria data/document could be used
for used in clinical practice and also future meta-analysis

From where data/document is obtainable
Ebrahim Salehifar Email: Esalehifar52@gmail.com

What processes are involved for a request to access data/document
sending email to Dr Ebrahim Salehifar

Comments