Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Curcumin effects on the prevention of peripheral neuropathy-induced by chemotherapy regimen containing paclitaxel in breast cancer patients; a randomized, double blinded and placebo-controlled clinical trial

Protocol summary

Study aim

The effect of nanocurcumin in reducing the side effects of chemotherapy with taxane drugs, especially neuropathy in patients with breast cancer.

Design

In the intervention group, patients received 40 mg nanocurcumin capsules three times a day for 2 months. Also, in the parallel placebo group, patients use nanocurcumin drug placebo three times a day

Settings and conduct

Clinical trial - Isfahan University of Medical Sciences

Participants/Inclusion and exclusion criteria

Inclusion criteria - All adult women (18 years and older and less than 65 years old) with non-metastatic breast cancer - Patients who do not have any history of liver and kidney failure Exclusion criteria - Patients with a history of any peripheral neuropathy - Patients with a history of coronary artery disease and peripheral vascular disease - All diabetic patients - Pregnancy and breastfeeding - Chronic use of cigarettes, drugs or alcohol - Patients with a history of peripheral neuropathy (eg, hereditary, with nutritional factors and paraneoplastic causes) - Those who have received chemotherapy for another malignancy in the past. - Users of anti-platelet drugs such as aspirin, etc. and oral and injectable anti-thrombosis

Intervention groups

In the intervention group, patients received 40 mg nanocurcumin capsules three times a day for 2 months. Also, in the parallel placebo group, patients use nanocurcumin drug placebo three times a day

Main outcome variables

Prevention of peripheral neuropathy caused by paclitaxel-containing regimen

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180722040556N10**
Registration date: **2024-01-28, 1402/11/08**
Registration timing: **prospective**

Last update: **2024-01-28, 1402/11/08**
Update count: **0**

Registration date

2024-01-28, 1402/11/08

Registrant information

Name

Azadeh Moghaddas

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-04-03, 1403/01/15

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

Curcumin effects on the prevention of peripheral neuropathy-induced by chemotherapy regimen containing paclitaxel in breast cancer patients; a randomized, double blinded and placebo-controlled clinical trial

Public title

Curcumin effects on the prevention of peripheral neuropathy-induced by chemotherapy regimen containing paclitaxel in breast cancer patients; a randomized, double blinded and placebo-controlled clinical trial

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

All adult women (18 years and older and less than 65 years old) with non-metastatic breast cancer who received paclitaxel at a dose of 175 mg/m2 every 3 weeks for 4 courses after completing an anthracycline-containing regimen for the first time in the treatment process (New case patients). The patient must have compliance in taking medication for at least 8 weeks and have enough ability to swallow and consume nanocurcumin capsules orally. Patients should have the necessary literacy to fill in the questionnairesand also have the necessary cooperation in performing neurological tests. Patients who do not have any history of liver and kidney failure.

Exclusion criteria:

Patients with a history of any peripheral neuropathy Patients with a history of coronary artery disease and peripheral vascular disease All diabetic patients Pregnancy and breastfeeding taking anticonvulsant drugs, Tricyclic antidepressants, other neuropathic pain relievers such as duloxetine Chronic use of cigarettes, drugs or alcohol Patients with a history of peripheral neuropathy (eg, hereditary, with nutritional factors and paraneoplastic causes) Those who have received chemotherapy for another malignancy in the past. Metastasis to the central nervous system or any neurological involvement due to metastasis or tumor pressure Users of anti-platelet drugs such as aspirin, etc. and oral and injectable anti-thrombosis

Age

From **18 years** old to **65 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization of the samples will be based on Blocked randomization method. Information such as the number of treatment groups (two main intervention groups for example A and placebo for example B), The size of the blocks (a multiple of the number of groups that will be chosen in this study to reduce the complexity of the work, size 4) and the total number of patients (sample size of 33 people) to the internet software machines specific for this calculation (for example, available at https://www. .sealedenvelope.com/simple-randomiser/v1/lists) will be imported and According to the codes obtained by the final analysis, a code will be assigned to each patient who enters the study, which will determine the type of group that should take medicine or placebo. Blocking is usually used in order to balance the number of samples allocated to each of the studied groups. In this method, equal blocking will be used. In this way, the samples are randomized in two groups as much as possible. After the end of sampling, the code of each patient is opened and matched with the output of the software, and it is tried as much as possible so that the person who collects the information and the interventionist knows about the code information of the drugs after analyzing the data.

Blinding (investigator's opinion)

Double blinded

Blinding description

Nanocurcumin capsule (40mg) and placebo will be provided by "Exir Nano Sina" company. Each nanocurcumin capsule contains (72% curcumin, 25% demethoxycurcumin, 3% bismethoxycurcumin). Each placebo capsule contains (polysorbate 80). The placebo and the original drug will be identical in all respects. Both are prepared from the same factory so that the drug and the placebo are placed in the same package, thus the blinding method can be done well. Then placebo and supplement products with a specified number for a patient (Assuming to complete the entire duration of the course with a dose three times a day) will be provided to the student with a special code. The information of this specific code on the drug packages is only available to the main project manager, who is not involved in sampling, and other colleagues (patients, students, doctors who perform clinical evaluation) do not know about these codes.Therefore, sampling will be done with a blind method.

Placebo

Used

Assignment

Parallel

Other design features

This study is a clinical trial that is controlled with placebo and double-blind. The collection of samples is expected to take 1 year and This collection will be done on patients in the hematology-oncology center of Seyed al-Shohada Hospital or affiliated clinics of this hospital. Seyyed al-Shohada Hospital is a specialized 200-bed hospital and a reference in the field of treating patients with blood cancers or solid tumors and related problems located in Isfahan city. It is also well equipped in terms of medical staff and necessary facilities to treat such patients.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of isfahan university of medical sciences

Street address
Isfahan University of medical Scienices, hezar jarib street, Isfahan, Iran

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isfahan

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Postal code
8174673461

Approval date
2023-04-25, 1402/02/05

Ethics committee reference number
IR.MUI.RESEARCH.REC.1402.020

Health conditions studied

1

Description of health condition studied
Breast cancer patients

ICD-10 code
Malignant

ICD-10 code description
(C50-C50)

Primary outcomes

1

Description
Determining and comparing the severity of neuropathy before and after the intervention in each of the intervention and placebo groups

Timepoint
Before the start of chemotherapy - before the second cycle of chemotherapy - before the third cycle of chemotherapy

Method of measurement
Determining and comparing the mean score of NSS, NDS and MNSI index, and comparing neurological tests before and after the intervention

Secondary outcomes

empty

Intervention groups

1

Description
In the intervention group, patients received 40 mg nanocurcumin capsules three times a day for 2 months.

Category
Prevention

2

Description
in placebo group, patients use nanocurcumin drug placebo three times a day

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Seyyed al-Shohda teaching Hospital

Full name of responsible person
Azadeh Moghaddas

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hezarjarib

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
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Grant name
En Vice-Chancellery for Research of Isfahan University of

Medical Sciences

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Azadeh moghaddas

Position

Assistant Professor Of Clinical Pharmacy

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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Azadeh moghaddas

Position

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Latest degree

Specialist

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

All collected data

When the data will become available and for how long

From the july of 2024

To whom data/document is available

All academic centers

Under which criteria data/document could be used

All documents with citation

From where data/document is obtainable

E-mail address

What processes are involved for a request to access data/document

After sending a request, we will call the related person and the data will be revealed in less than one week.

Comments