

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The application of metformin in protecting chemotherapy-induced neuropathy in patients with breast cancer

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

The effect of metformin on protecting against chemotherapy-induced neuropathy in breast cancer patients

Design

This double-blind randomized clinical trial is conducted with a control group and parallel groups, phases 3 and 2, on 40 patients.

Settings and conduct

The study setting is the Gynecologic Oncology Ward of Baqaei 2 Hospital, Ahvaz, Iran. The patients are also sampled and transferred to the laboratory unit as a code.

Participants/Inclusion and exclusion criteria

To conduct this study, a group of newly diagnosed cases with breast cancer referred to Baghei 2 Hospital, Ahvaz, Iran, undergoing the paclitaxel chemotherapy regimen, are included. The definitive diagnosis of breast cancer in these people is also made through the biopsy findings. The exclusion criteria in this study are: 1. Active diabetes or its history 2. The history of neuropathy or nerve damage 3. Anemia 4. The history of chemotherapeutic agent used 5. Hyperthyroidism or thyrotoxicosis 6. The patients with digestive problems who were less likely to tolerate metformin 7. The patients with contraindications for metformin treatment

Intervention groups

Breast cancer patients undergoing paclitaxel chemotherapy

Main outcome variables

Metformin may prevent neuropathy in patients with breast cancer treated with paclitaxel.

Last update: **2021-11-20, 1400/08/29**

Update count: **0**

Registration date

2021-11-20, 1400/08/29

Registrant information

Name

hosein karimpoorian

Name of organization / entity

medical unevirsity of ahvaz

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-06, 1400/08/15

Expected recruitment end date

2021-12-21, 1400/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The application of metformin in protecting chemotherapy-induced neuropathy in patients with breast cancer

Public title

The application of metformin in protecting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151021024645N3**

Registration date: **2021-11-20, 1400/08/29**

chemotherapy-induced neuropathy

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients affected with breast cancer, based on the biopsy findings,
Exclusion criteria:
 Active diabetic patients or those with a history of diabetes The history of neuropathy or nerve damage
 Anemia The history of chemotherapeutic agent use
 Hyperthyroidism or thyrotoxicosis The patient with digestive problems who may less likely tolerate metformin
 The patients with contraindications for metformin treatment

Age
From **18 years** old

Gender
Female

Phase
2-3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
 Randomization method: Block randomization using 2 and 4 blocks (randomly)
 Randomization unit: Individual
 Randomization tool: Web application or software
 Description of allocation concealment: Using opaque sealed envelopes with a random sequence

Blinding (investigator's opinion)
Double blinded

Blinding description
 The laboratory collaborators are not aware of the intervention and control people, and the samples are given to them with a code. The patients are also unaware of the potential benefits of using metformin to protect against neuropathy because they have to complete a questionnaire.

Placebo
Not used

Assignment
Parallel

Other design features
 The study subjects are divided into two groups, receiving routine chemotherapy. In the intervention group, metformin is used in addition to routine chemotherapy, at the beginning of the study (before the intervention), at the end of cycle 6, and the end of cycle 12.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz jundishapur University of Medical Sciences

Street address

Golestan

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2021-10-17, 1400/07/25

Ethics committee reference number

IR.AJUMS.REC.1400.441

Health conditions studied

1

Description of health condition studied

Breast cancer

ICD-10 code

2C6Z

ICD-10 code description

Carcinoma of breast, specialised type

Primary outcomes

1

Description

Severity of neuropathy

Timepoint

At the beginning of the study and in cycles 2, 4, 6, 8, 10 and 12

Method of measurement

PNQ questionnaire, CTCAE questionnaire

2

Description

Laboratory parameters

Timepoint

At the beginning of the study (before the intervention), the end of cycle 6 and the end of cycle 12.

Method of measurement

Laboratory evaluation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The drug is metformin, prescribed in

the form of three tablets of 500 mg per day (1500 mg per day in total) for three months from the first day of chemotherapy. Due to the availability of the medicine, it is prepared from the best available in the market.

Category

Prevention

2**Description**

Control group: This group only uses the paclitaxel chemotherapy regime for three months.

Category

Diagnosis

Recruitment centers**1****Recruitment center****Name of recruitment center**

Baghaei 2 hospital

Full name of responsible person

Dr. Hossein Karimpourian

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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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

Ahvaz 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**

Ahvaz University of Medical Sciences

Full name of responsible person

Hossein Karimpourian

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Position

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Latest degree

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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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

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

No - There is not a plan to make this available

Analytic Code

No - There is not 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

The results of the questionnaire are published in full.

Some laboratory results are published.

When the data will become available and for how long

Access is open six months after the article is published.

To whom data/document is available

Given the importance of the study, everyone can have access

Under which criteria data/document could be used

The use of data is only permitted for modeling in a similar study.

From where data/document is obtainable

The data can be accessed by contacting

Daryushpurrahrman@gmail.com

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

Mention the purpose of the request and introduce the people who have access to the data.

Comments