

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of the N-acetyl cysteine versus placebo on prevention and control of chemotherapy induced neuropathy in patients with breast cancer: a triple-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of the N-acetyl cysteine versus placebo on prevention and control of chemotherapy induced neuropathy in patients with breast cancer

Design

This is a triple-blind randomized clinical trial, phase II, in which 102 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients with breast cancer referring to the Imam Khomeini Clinic in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the drawing of lots. This trial will be triple-blinded so that neither patients nor the physician examining the patients and statistical analyzer will be aware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age range: 18 to 80 years old; be candidate for chemotherapy. Exclusion criteria: history of neuropathy with grade greater than one; behavioral disorders; history of chemotherapy; history of asthma.

Intervention groups

Intervention group: tablet N-acetyl cysteine (manufactured by Darman Yab Daru Pharmaceutical Co.) 1200 mg twice daily one day before chemotherapy with Taxane until one day after that. Control group: tablet placebo (manufactured by School of Pharmacy, Shahid Beheshti University of Medical Science) twice daily one day before chemotherapy with Taxane until one day after that.

Main outcome variables

Severity of neuropathy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N377**

Registration date: **2021-01-25, 1399/11/06**

Registration timing: **prospective**

Last update: **2021-01-25, 1399/11/06**

Update count: **0**

Registration date

2021-01-25, 1399/11/06

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-03, 1399/11/15

Expected recruitment end date

2022-01-05, 1400/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of the N-acetyl cysteine versus placebo on prevention and control of chemotherapy induced neuropathy in patients with breast cancer: a triple-blind randomized clinical trial

Public title

Effect of the N-acetyl cysteine versus placebo on prevention and control of chemotherapy induced neuropathy in patients with breast cancer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age: 18 to 80 years old Candidate for chemotherapy

Exclusion criteria:

History of neuropathy with grade greater than one
Behavioral disorders History of chemotherapy History of asthma

Age

From **18 years** old to **80 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **102**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "intervention" on one sheet and "control" on another. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention or control group.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The shape of the medications and placebos will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The care provider who will deliver the medications and the physician who will examine the patients will not be aware of the intervention. The analyzer will be unaware of the type of interventions. Thus, the trial will be run as triple-blind

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2020-09-19, 1399/06/29

Ethics committee reference number

IR.UMSHA.REC.1399.534

Health conditions studied

1

Description of health condition studied

Neuropathy

ICD-10 code

G60.3

ICD-10 code description

Idiopathic progressive neuropathy

Primary outcomes

1

Description

Severity of neuropathy

Timepoint

Before chemotherapy and three weeks after that

Method of measurement

Using the NCI-CTCAE v4.0 scale and Visual Analog Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: tablet N-acetyl cysteine (manufactured by Darman Yab Daru Pharmaceutical Co.) 1200 mg twice daily one day before chemotherapy with Taxane until one day after that

Category

Treatment - Drugs

2

Description

Control group: tablet placebo (manufactured by School of Pharmacy, Shahid Beheshti University of Medical Science) twice daily one day before chemotherapy with Taxane until one day after that

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Clinic in Hamadan city

Full name of responsible person

Elyas Hassanzade

Street address

Imam Khomeini Clinic, Mirzadeh Eshghi Ave.

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6517838695

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elyas.hassanzade@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeid Bashirian

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Elyas Hassanzade

Position

Medical Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Abdolazim Sedighi Pashaki

Position

Radiotherapist

Latest degree

Medical doctor

Other areas of specialty/work

Radiotherapy

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Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available