

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 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)

##### Phone

+98 81 1838 0090

##### Email address

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#### 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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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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Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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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