Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of N acetylcysteine on the prevention of peripheral neuropathy induced by taxanes : a randomized double-blind placebo- controlled trial

Protocol summary

Study aim

Evaluation of the protective effect of N-acetylcysteine in peripheral neuropathy caused by chemotherapy with taxanes

Design

A Clinical trial with two parallel groups, with a control group, with placebo, double-blind, phase 3, with a sample size of 60 people. Randomization with the help of Excel software and quadruple blocks.

Settings and conduct

In order to investigate the preventive effect of N-acetylcysteine in peripheral neuropathy caused by taxanes in patients receiving AC-T regimen in Imam Khomeini Hospital, Sari. This study has two arms of medicine and placebo, and a four-digit code is assigned to each patient through the Excel program.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who are candidates for AC-T regimen, over 18 years of age, with normal baseline bone marrow, liver, kidney, and heart function. Exclusion criteria: Patients with a previous history of neurological diseases, neuropathic pain, renal clearance above 30, severe liver failure, heavy alcohol and opioid users, pregnant and lactating women, uncontrolled diabetes.

Intervention groups

intervention group: N-Acetylcysteine (NAC) Effervescent Tablets, 1200 mg, 24 hours before chemotherapy and on the day of chemotherapy, one hour before receiving taxane in each cycle Control group: Placebo NAC effervescent tablet 1200 mg one day before and one hour before receiving taxane in each cycle

Main outcome variables

severity of peripheral neuropathy; pain intensity; Quality of Life ; Serum level of oxidative factors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090613002027N20**
Registration date: **2023-04-16, 1402/01/27**
Registration timing: **prospective**

Last update: **2023-04-16, 1402/01/27**
Update count: **0**

Registration date

2023-04-16, 1402/01/27

Registrant information

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2024-02-19, 1402/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of N acetylcysteine on the prevention of peripheral neuropathy induced by taxanes : a randomized double-blind placebo- controlled trial

Public title

protective effect of N-acetylcysteine on taxane neuropathy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

AC-T regimen recipient People over 18 years old For normal bone marrow function (ANC>1500/mm3 and Plt>100000//mm3) Having normal liver function (bili<1.5 mg/dl - liver enzymes level less than three times the maximum normal range) and normal kidney function (cr<1.5 mg/dl) Normal baseline ECG

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. Creatinine clearance less than 30 ml/min Severe liver failure (liver enzymes more than three times the normal limit) History of allergy and sensitivity to N-acetylcysteine Uncontrolled diabetes Alcoholic patients chronic use of vitamin B1 and supplements containing magnesium Taking antiepileptic drugs Use of opioids 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
- Investigator
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

onsidering the effect of the type of chemotherapy drug on the prevalence and severity of peripheral neuropathy, in order to adjust this intervening factor, stratification was performed based on the received taxane (Paclitaxel or Docetaxel) and randomization to receive acetylcysteine or placebo as It will be done separately in patients receiving paclitaxel and docetaxel. Patients will be placed in two groups, placebo and drug, by Block Balanced Randomization (BBR) method. Using the free web-based system http://www.randomization.com/, the data allocation sequence will be obtained. In this way, the number of subjects in each block is determined to be 4, and the letter A will be used for the control group and the letter B will be used for the test group, and the allocation sequence for 60 samples will be created in 15 blocks of 4 by combining the letters A and B. In order to hide the allocation (Allocation Concealment) using the random number table, a random 4-digit number will be determined as the unique code of each patient so that the grouping status of the patient (A or B) remains hidden. The information about the blocks and the specific code of each patient will be available only to the first operator. The patient, the clinical pharmacy assistant who is in charge of clinical evaluations, and the statistical analyst will not know about the grouping of patients. NAC and placebo drugs will be pre-packaged according to the assigned codes and will be given to the participants after randomization by the clinical pharmacy assistant. Arrangements will be made for all patients to use NAC from a pharmaceutical company.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study will be double blind. In this way, the patient, doctor and clinical assistants will not know about the drug used (N-acetylcysteine or placebo). Medicines and placebos are prepared from a same pharmaceutical company and are provided to patients in similar packages marked with a 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

Farah abad Ave, Mazandaran university of Medical Sience

City

Sari

Province

Mazandaran

Postal code

4815733971

Approval date

2023-01-24, 1401/11/04

Ethics committee reference number

IR.MAZUMS.REC.1401.519

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 the beginning of the study, the end of the 4th cycle and one month after the end of the drug regimen
Method of measurement
based on NCI CTCAE version 5 , FACT/GOG-Ntx , Neuropathy pain scale

2

Description
intensity of pain
Timepoint
At the beginning of the study, the end of the 4th cycle and one month after the end of the drug regimen
Method of measurement
based on Numeric pain rating scale

Secondary outcomes

1

Description
quality of life
Timepoint
At the beginning of the study, the end of the 4th cycle and one month after the end of the drug regimen
Method of measurement
based on EORTC QLQ-C30 version 3

2

Description
Serum level of glutathione
Timepoint
At the beginning of the study and at the end of 4th cycle
Method of measurement
blood sample

3

Description
Serum level of capacity of antioxidant enzymes
Timepoint
At the beginning of the study and at the end of 4th cycle
Method of measurement
blood sample

4

Description
Serum level of lipid peroxidation
Timepoint
At the beginning of the study and at the end of 4th cycle
Method of measurement
blood sample

5

Description
level of nitric oxide
Timepoint
At the beginning of the study and at the end of 4th cycle
Method of measurement
blood sample

Intervention groups

1

Description
Intervention group: Acetylcysteine effervescent tablets made by Oswe company, 1200 mg 24 hours before chemotherapy and on the day of chemotherapy, one hour before receiving taxane drugs in each cycle
Category
Prevention

2

Description
Control group: Effervescent tablets of placebo N-acetylcysteine made by Oswe company 1200 mg one day before and one hour before receiving taxane drugs in each cycle
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

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