

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparative study of the effect of 25 mg zinc tablets with placebo on the rate of prevention of acute peripheral neuropathy in cancer patients treated with taxanes

Protocol summary

Study aim

Determining the effect of 25 mg zinc capsule with placebo on the prevention of acute peripheral neuropathy in cancer patients treated with taxanes

Design

A clinical trial with two intervention groups, in parallel groups, double-blind, randomized with a simple method, with sample size 60

Settings and conduct

At the beginning of the study, all patients of Isfahan Hematology Clinics will be taught about how to conduct the study and the form of conscious satisfaction will be completed by the patients. Then, the demographic information of the patients, the information about the type and stage of the patient's cancer and the diet and the dose of the patient's chemotherapy, as well as the information about the patient's neuropathy score at the beginning of the study will be recorded. In order to randomly select patients in two groups, a numbered number was provided for each patient (from 1 to 152) and the blocking and stratification methods for random distribution of patients based on their number in the intervention groups and We use placebo. The patient is referred to the hospital every 3 weeks for 3 months (3 follow-up sessions) and then, based on the Criteria for side effects (CTCAE) version 5.0, the degree of neuropathy is examined and evaluated and all information will be recorded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Cancer confirmed by biopsy and candidate for chemotherapy containing taxan; Be able to give informed consent; The patient's performance status should be such that he or she can describe the condition; Exclusion criteria: They have diabetes, neurological disorders or neuropathy

Intervention groups

We have two intervention groups. One group received

placebo and the other group received zinc capsules.

Main outcome variables

neuropathy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200422047166N1**

Registration date: **2020-06-10, 1399/03/21**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-10, 1399/03/21**

Update count: **0**

Registration date

2020-06-10, 1399/03/21

Registrant information

Name

Farshad Fardani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3650 1072

Email address

farshadfardani@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-25, 1399/03/05

Expected recruitment end date

2020-11-25, 1399/09/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the effect of 25 mg zinc tablets with placebo on the rate of prevention of acute peripheral neuropathy in cancer patients treated with taxanes

Public title

Effect of zinc tablets in the prevention of acute peripheral neuropathy in cancer patients treated with taxanes

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Cancer confirmed by biopsy and candidate for chemotherapy containing taxan Be able to give informed consent. The patient's performance status should be such that he or she can describe the condition.

Exclusion criteria:

They have diabetes, neurological disorders or neuropathy

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

The study sample is randomly selected and then randomly assigned to the intervention and control group using individual and pair blocks.

Blinding (investigator's opinion)

Double blinded

Blinding description

Envelopes will be given to patients at random. The patient then delivers the envelope to the drug distributor, where the patient code is recorded. It should be noted that the patient will not be aware of the nature of their medication (medication or placebo) and the physician collecting the study information (internal medicine assistant) will not know the patient's code (the study is two-course).

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahn University of Medical Sciences, Hezar Jarib st, Isfahan

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Province

Isfahan

Postal code

7346181746

Approval date

2020-02-29, 1398/12/10

Ethics committee reference number

IR.MUI.MED.REC.1398.613

Health conditions studied**1****Description of health condition studied**

Drug-induced polyneuropathy

ICD-10 code

G62.0

ICD-10 code description

Drug-induced polyneuropathy

Primary outcomes**1****Description**

Severity of neuropathy

Timepoint

Every 3 weeks for 3 months

Method of measurement

Criteria for side effects table

2**Description**

Acute neuropathy

Timepoint

Every 3 weeks for 3 months

Method of measurement

Examination

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Patients in the control group receive placebo capsule (25 mg) daily for two hours after lunch for 12 weeks.

Category

Placebo

2

Description

Intervention group: Patients in the intervention group receive 25 mg of zinc sulfate capsule (Alhavi Pharma) daily for two hours after lunch for 12 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hematology clinics

Full name of responsible person

Ali Haji Gholami

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Isfahan hematology clinics

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjooy Javanmard

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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

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

Ali Haji Gholami

Position

Assistant Professor of Hematology & Oncology

Latest degree

Subspecialist

Other areas of specialty/work

Hematology

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Person responsible for scientific inquiries

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Person responsible for updating data**Contact****Name of organization / entity**

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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