

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Investigating and comparing the therapeutic effect of Nevazin and vitamin B1 in chemotherapy-induced neuropathy in cancer patients undergoing chemotherapy

Protocol summary

Study aim

Determining the therapeutic effect of Nevazin and vitamin B1 in chemotherapy-induced neuropathy

Design

A clinical trial with a control group, with parallel groups, randomized, phase 3, 27 samples in each group. Allocation of samples to intervention groups is done using random blocks method with blocks of size 6

Settings and conduct

In present study cancer patients with neuropathy symptoms are selected from the chemotherapy department of Qazvin Velayat hospital. Blinding was not done in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All cancer patients who are undergoing chemotherapy and have neuropathy. Exclusion criteria: use of other drugs effective in improving neuropathy such as Gabapentin, Pregavalin, Duloxetine.

Intervention groups

Intervention Group: Daily prescription of one 150 mg Nevazin tablet produced by Pars Gita Daru Company for three months. Control Group: Daily prescription of one 150 mg Vitamin B1 tablet produced by Razak Company for three months.

Main outcome variables

Severity of neuropathy after chemotherapy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230722058878N1**

Registration date: **2023-09-04, 1402/06/13**

Registration timing: **prospective**

Last update: **2023-09-04, 1402/06/13**

Update count: **0**

Registration date

2023-09-04, 1402/06/13

Registrant information

Name

Seyyed Aboozar Mousavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3333 6001

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-21, 1402/06/30

Expected recruitment end date

2024-02-20, 1402/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating and comparing the therapeutic effect of Nevazin and vitamin B1 in chemotherapy-induced neuropathy in cancer patients undergoing chemotherapy

Public title

The effect of Nevazin and vitamin B1 in treatment of chemotherapy-induced neuropathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All cancer patients who are undergoing chemotherapy

Exclusion criteria:

People who are allergic to medicines containing vitamin B
use of other drugs effective in improving neuropathy
such as Gabapentin, Pregavalin, Duloxetine

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 54

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are assigned to two treatment groups A and B using the method of random blocks (Balance block randomization), the size of each block is 6 and the total number of blocks is 9. Sealedenvelope.com will be used to implement block randomization.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qazvin University of Medical Sciences

Street address

Research and Technology deputy, Mavaddat Alley, Shahid Beheshti Blvd, Qazvin

City

Qazvin

Province

Qazvin

Postal code

3413996134

Approval date

2023-08-30, 1402/06/08

Ethics committee reference number

IR.QUMS.REC.1402.140

Health conditions studied

1

Description of health condition studied

neuropathy

ICD-10 code

G62.0

ICD-10 code description

Drug-induced polyneuropathy

2

Description of health condition studied

chemotherapy

ICD-10 code

Z51.11

ICD-10 code description

Encounter for antineoplastic chemotherapy

Primary outcomes

1

Description

Severity of neuropathy after chemotherapy

Timepoint

Before and after treatment

Method of measurement

Valk questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Daily prescription of one 150 mg Nevazin tablet produced by Pars Gita Daru Company for three months

Category

Treatment - Drugs

2

Description

Control group: Daily prescription of one 150 mg Vitamin B1 tablet produced by Razak Company for three months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Velayat hospital

Full name of responsible person

Seyyed Aboozar Mousavi

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22 Bahman Blvd., Minoodar region

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Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Seyyed Mehdi Mirhashemi

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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

Qazvin 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

Iran University of Medical Sciences

Full name of responsible person

Seyyed Aboozar Mousavi

Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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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