Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

The efficacy and safety of Silymarin in chemotherapy-induced peripheral neuropathy (CIPN): a randomized double-blind clinical trial study

Protocol summary

Study aim

The efficacy and safety of Silymarin in chemotherapy-induced peripheral neuropathy (CIPN)

Design

Patients with historically confirmed diagnosis of cancer having CIPN who refer to the outpatient oncology department of Sari Hospital, Iran will receive Silymarin or placebo in groups of intervention and control, respectively, and quality of life, pain and neuropathy intensity will be assessed by Quality of life Questionnaire (EORTC QLQ), Visual Analogue Scale (VAS), and Common Terminology Criteria for Adverse Event (CTCAE) criteria, respectively.

Settings and conduct

This is a double-blind, placebo-controlled study on patients with confirmed diagnosis of cancer who are having CIPN. Patients and care provider are unaware of the type of interventions. The drug and placebo are coded in unknown bottles and will be handed to patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with histologically confirmed diagnosis of cancer, at least 18 years of age, and having CIPN will be included in the study. Exclusion criteria: patients predisposing to neuropathy, including diabetes, neuromuscular disease, vitamin B12 deficiency, amyloidosis, and connective tissue disease, hereditary and acquired neuropathies, unbearable side effects of the drug or drug reaction, taking any antioxidant supplement in the last two months, pregnancy, or breastfeeding will be excluded from the study.

Intervention groups

Interventional group will receive 140 mg/day of the silymarin (Gol daru, Iran) in two daily doses with 300 mg/day Gabapentin as a standard treatment for peripheral neuropathy, while the control group will receive 300 mg/day of Gabapentin with placebo (microcrystalline cellulose) every 12 hours per day. Both groups will receive the drug for 3 months.

Main outcome variables

Patient's neuropathy intensity after intervention base on CTCAE criterion.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201128049515N1**
Registration date: **2020-12-17, 1399/09/27**
Registration timing: **prospective**

Last update: **2020-12-17, 1399/09/27**
Update count: **0**

Registration date

2020-12-17, 1399/09/27

Registrant information

Name

Ramin shekarriz

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3336 4044

Email address

r.shekarriz@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The efficacy and safety of Silymarin in chemotherapy-induced peripheral neuropathy (CIPN): a randomized double-blind clinical trial study

Public title
The efficacy and safety of Silymarin in chemotherapy-induced peripheral neuropathy (CIPN)

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Histologically confirmed diagnosis of cancer At least 18 years of age Having chemotherapy-induced peripheral neuropathy (CIPN).

Exclusion criteria:
Having a known disease predisposing to neuropathy, including diabetes, neuromuscular disease, vitamin B12 deficiency, amyloidosis, and connective tissue disease, a history of neurological diseases such as hereditary and acquired neuropathies Unbearable side effects of the drug or drug reaction Taking any antioxidant supplement in the last two months Pregnancy, or breastfeeding unwillingness to attend the study

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Those patients who give consent to enter the study will be randomized into blocks of four and sequentially numbered. The randomization code will be held by a third party. Then they will be categorized in two groups of intervention (Silymarin + Gabapentin) and control (Placebo + Gabapentin). Silymarin and placebo will be kept in bottles with previously defined codes and will be handed to participants randomly.

Blinding (investigator's opinion)
Double blinded

Blinding description
This is randomized, double-blind study. Patients and care provider will not be aware of the type of medication (Silymarin or placebo). Patients will be coded randomly into groups of intervention and control separately and their data will be kept in a computer with password. Care provider and patients will not have access to any of these data. Silymarin and placebo will be put in bottles based on patient's code and then will be handed to care provider and then to the patients monthly with no mention to the type of the medicine. Blinding will be applied till the end of the study and statistic analysis.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic committee of Mazandaran University of Medical sciences

Street address
Comprehensive Cancer Center, Imam hospital, Amir Mazandarani Blvd, Sari, Iran

City
Sari

Province
Mazandaran

Postal code
4816633131

Approval date
2019-11-27, 1398/09/06

Ethics committee reference number
IR.MAZUMS.IMAMHOSPITAL.REC.1398.6176

Health conditions studied

1

Description of health condition studied
Chemotherapy induced peripheral neuropathy in confirmed diagnosed cancer patients.

ICD-10 code
G61.1

ICD-10 code description
Serum neuropathy

Primary outcomes

1

Description
Neuropathy intensity

Timepoint
The first day and 3rd month after the onset of the intervention

Method of measurement
Common Terminology Criteria for Adverse Events (CTCAE) criterion and questionnaire

Secondary outcomes

1

Description
Quality of life
Timepoint
The first day and the 3rd month after the start of the intervention
Method of measurement
European Organization for Research and Treatment of Cancer quality of life questionnaire (EORTC QLQ)

2

Description
Pain intensity
Timepoint
The first day and 3rd month after the start of the intervention
Method of measurement
Visual analysis scale (VAS) criterion and questionnaire

Intervention groups

1

Description
Intervention group: 140 mg/day of silymarin (Gol Daru Company, Iran) in two daily doses with 300 mg/day Gabapentin as a standard treatment for peripheral neuropathy for 3 month. Both medications are orally prescribed.
Category
Treatment - Drugs

2

Description
Control group: 300 mg/day of Gabapentin with 140 mg/day of placebo (microcrystalline cellulose) in two daily doses for 3 months. Both medications are orally prescribed.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam hospital
Full name of responsible person
Ramin Shekarriz
Street address
Cancer Lab, 3rd floor, Cancer comprehensive center, Imam hospital, Amir Mazandarani Blvd, Sari Town
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Dr. Majid Saeedi
Street address
Vice chancellor for research and technology, Moalem Sq, Sari, Iran
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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
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Dr Ramin Shekarriz
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Oncology
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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

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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's no further information.

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

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available