Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Evaluation of the effect of Livergol (silymarin extract) in reducing peripheral neuropathies induced by cisplatin in patients undergoing chemotherapy

Protocol summary

Study aim
Determining and comparing the effect of Livergol on reducing peripheral neuropathies induced by cisplatin in patients undergoing chemotherapy

Design
A randomized, double-blinding clinical trial, with the parallel groups, Phase 3 on 60 patients

Settings and conduct
In this randomized double-blind clinical trial study, 60 cancer patients undergoing cisplatin chemotherapy referred to Seyed Al-Shohada Hospital in Isfahan will be included in the study and will be randomly divided into 2 groups. In addition to cisplatin chemotherapy, one group will receive Livergol and the other group will receive a placebo. Then the chemotherapy induced peripheral neuropathy score of patients will be evaluated and compared between the two groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria include age over 18 years, newly diagnosed cancer and undergoing chemotherapy with cisplatin, have symptoms of peripheral neuropathy after starting chemotherapy and consent to participate in this study. Exclusion criteria include having multiple myeloma, having previous neurological disorders, and having diseases that give rise to peripheral neuropathy (such as diabetes).

Intervention groups
Intervention group: In addition to cisplatin chemotherapy, patients in this group will be treated with Livergol 140 mg tablets 3 times a day for 90 days.
Control group: In addition to cisplatin chemotherapy, patients in this group will receive placebo 3 times a day for 90 days.

Main outcome variables
Chemotherapy induced peripheral neuropathy score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200825048515N29**
Registration date: **2021-04-06, 1400/01/17**
Registration timing: **registered_while_recruiting**

Last update: **2021-04-06, 1400/01/17**
Update count: **0**

Registration date
2021-04-06, 1400/01/17

Registrant information

Name
Asieh Maghami Mehr

Name of organization / entity

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Iran (Islamic Republic of)

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+98 31 0000 0000

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asimaghami@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-04, 1400/01/15

Expected recruitment end date
2021-05-21, 1400/02/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of Livergol (silymarin extract) in reducing peripheral neuropathies induced by cisplatin in patients undergoing chemotherapy

Public title
Evaluation of the effect of Livergol in reducing peripheral neuropathies induced by cisplatin

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age over 18 years Newly diagnosed cancer and undergoing chemotherapy with cisplatin Having symptoms of peripheral neuropathy after starting chemotherapy Consent to participate in this study

Exclusion criteria:
Having multiple myeloma Having previous neurological disorders Having diseases that give rise to peripheral neuropathy (such as diabetes)

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, 60 eligible patients will be randomly selected. Then random numbers are created by computer software "Random Allocation". We randomly divide these numbers into two parts. Each number is written on paper and placed in an envelope. Then each patient is asked to choose an envelope from among the envelopes. According to the selected envelope, the patient will be assigned to one of the two groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the two drugs Livergol and placebo are prepared by the pharmacist with the same color, smell and shape and placed in coded packages and delivered to the patient, and the same instructions are prescribed to the patient. Also, the person recording the patient's clinical information and the statistical analyst will not be aware of the type of intervention.

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
Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq

City
Isfahan

Province
Isfehan

Postal code
8179964167

Approval date
2019-06-01, 1398/03/11

Ethics committee reference number
IR.MUI.MED.REC.1398.114

Health conditions studied

1

Description of health condition studied
Cancer

ICD-10 code
C80.1

ICD-10 code description
Malignant (primary) neoplasm, unspecified

Primary outcomes

1

Description
Chemotherapy induced peripheral neuropathy score

Timepoint
Before and after the intervention

Method of measurement
Chemotherapy Induced Peripheral Neuropathy Assessment Tool (CIPNAT)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In addition to cisplatin chemotherapy, patients in this group will be treated with Livergol 140 mg tablets 3 times a day for 90 days.

Category

Treatment - Drugs

2

Description
Control group: In addition to cisplatin chemotherapy, patients in this group will receive placebo 3 times a day for 90 days.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Seyed-al-Shohada Hospital of Isfahan
Full name of responsible person
Ali Haji Gholami
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Internal Medicine Department, Al-Zahra Hospital, Hezar Jerib Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Isfahan 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
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Ali Haji Gholami
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Assistant Professor
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Person responsible for updating data

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Latest degree
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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 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