# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 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**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 31 0000 0000

**Email address**

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
**Street address**
Internal Medicine Department, Al-Zahra Hospital, Hezar Jerib Street
**City**
Isfahan
**Province**
Isfehan
**Postal code**
8174675731
**Phone**
+98 31 3620 2020
**Email**
ali_hajigholami@yahoo.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Esfahan University of Medical Sciences
**Full name of responsible person**
Shaghayegh Haghjoo Javanmard
**Street address**
Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.
**City**
Isfahan
**Province**
Isfehan
**Postal code**
8174673461
**Phone**
+98 31 3668 8597
**Email**
dean@med.mui.ac.ir
**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
**Full name of responsible person**
Ali Haji Gholami
**Position**
Assistant Professor
**Latest degree**
Subspecialist
**Other areas of specialty/work**
Hematology
**Street address**
Internal Medicine Department, Al-Zahra Hospital, Hezar Jerib Street
**City**
Isfahan
**Province**
Isfehan
**Postal code**
8174675731
**Phone**
+98 31 3620 2020
**Email**
ali_hajigholami@yahoo.com

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Esfahan University of Medical Sciences
**Full name of responsible person**
Ali Haji Gholami
**Position**
Assistant Professor
**Latest degree**
Subspecialist
**Other areas of specialty/work**
Hematology
**Street address**
Internal Medicine Department, Al-Zahra Hospital, Hezar Jerib Street
**City**
Isfahan
**Province**
Isfehan
**Postal code**

8174675731

**Phone**

+98 31 3620 2020

**Email**

ali_hajigholami@yahoo.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Adele Dadkhah

**Position**

Non-faculty specialist physician

**Latest degree**

Specialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

Internal Medicine Department, Al-Zahra Hospital, Hezar Jerib Street

**City**

Isfahan

**Province**

Isfehan

**Postal code**

8174675731

**Phone**

+98 31 3620 2020

**Email**

dadkhah@yahoo.com

## 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