

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Evaluation of the therapeutic effects of livergol (silymarin) on the neuropathy caused by chemotherapy drugs (cisplatin, oxaliplatin and paclitaxel) in patients admitted to Education & Treatment Center of Valiasr.

Protocol summary

Study aim

Evaluation of the therapeutic effects of livergol (silymarin) on the neuropathy caused by chemotherapy drugs (cisplatin, oxaliplatin and paclitaxel)

Design

Randomized double blind clinical trial with intervention and placebo (single center)

Settings and conduct

In this randomized clinical trial (RCT) study, 70 patients with cancer who will receive either taxol or cisplatin and oxaliplatin-based chemotherapy regimens will be studied. First, the tibial, peroneal, and sural nerves will be evaluated by a neurologist for the severity of the involvement and the presence of neuropathy. Patients will be randomly divided into four groups using randomized blocks of four: one group will receive one daily Liverpool tablet (containing 1 mg silicarin for three months) along with chemotherapy regimen, and the second group will receive placebo. They will receive chemotherapy regimens. Electrophysiological status (including amplitude, latency, cv of the tibial, perianal and sural nerves) and subjective reporting of symptoms before and after treatment and three months after treatment will be compared between the two groups.

Participants/Inclusion and exclusion criteria

Entry requirements 1) Age range 40-75 years 2) Patients with cancers receiving oxaliplatin, cisplatin or paclitaxel-based chemotherapy regimens 3) Patients with concussions admitted to Valiasr educational center or referred to Valiasr Oncology Clinic Exit conditions 1)En Liverpool contraindication 2)The presence of peripheral peripheral neuropathy continues to be the treatment that needs to be changed with chemotherapy regimens 3) Other underlying etiologies of neuropathy

Intervention groups

Intervention group received livergol tablet (140mg) once

a day for three months; control group received placebo once a day for three months.

Main outcome variables

Quality of life, treatment efficacy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190427043389N3**

Registration date: **2020-02-01, 1398/11/12**

Registration timing: **prospective**

Last update: **2020-02-01, 1398/11/12**

Update count: **0**

Registration date

2020-02-01, 1398/11/12

Registrant information

Name

Hamed Ghavimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3347 3635

Email address

ghavimih@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2020-04-20, 1399/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the therapeutic effects of livergol (silymarin) on the neuropathy caused by chemotherapy drugs (cisplatin, oxaliplatin and paclitaxel) in patients admitted to Education & Treatment Center of Valiasr.

Public title

Evaluation of the therapeutic effects of livergol (silymarin) on the neuropathy caused by chemotherapy drugs.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age range 35-75 years Patients with cancers receiving oxaliplatin, cisplatin or paclitaxel-based chemotherapy regimens Patients with concussions admitted to Valiasr educational center or referred to Valiasr Oncology Clinic

Exclusion criteria:

Liverpool contraindication The presence of peripheral neuropathy continues to be the treatment that needs to be changed with chemotherapy regimens Other underlying etiologies of neuropathy

Age

From **35 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted block randomization with each block size is four.

Blinding (investigator's opinion)

Double blinded

Blinding description

The clinical trial will be planned in such a way that the participant and the clinical caregiver do not know which of the two control or test groups belongs.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zanjan University of Medical Sciences

Street address

Nxt. Ayatollah mousavi Hospital, Gavazang Blvd. Zanjan, Iran.

City

zanjan

Province

Zanjan

Postal code

56184- 45139

Approval date

2019-11-13, 1398/08/22

Ethics committee reference number

IR.ZUMS.REC.1398.339

Health conditions studied

1

Description of health condition studied

Chemotherapy

ICD-10 code

Z51.11

ICD-10 code description

Encounter for antineoplastic chemotherapy

Primary outcomes

1

Description

Evaluation of the effect of Levergol on the outcome of neuropathy in patients with concussion undergoing chemotherapy with oxaliplatin and paclitaxel

Timepoint

three months.

Method of measurement

FACT/GOG-NTX

Secondary outcomes

1

Description

Determination of quality of life in livergol recipient group

Timepoint

three months

Method of measurement

FACT/GOG-NTX

Intervention groups

1

Description

Intervention group: received livergol tablet produced by Goldarou Co. (140 mg) once a day for three months

Category

Treatment - Drugs

2

Description

Control group: received placebo tablet produced by Goldarou Co. once a day for three months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Education and treatment center of Valiasr

Full name of responsible person

Hamed Ghavimi

Street address

valiasr hospital.valiasr square.zanjan.Iran

City

zanjan

Province

Zanjan

Postal code

77978-45157

Phone

+98 24 3377 0801

Email

Hamed.ghavimi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr Alireza Shoghli

Street address

Azadi Square, Central Building of Zanjan University of Medical Sciences

City

zanjan

Province

Zanjan

Postal code

45156-13191

Phone

+98 24 3342 0677

Email

shoghli@zums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Zanjan University of Medical Sciences

Proportion provided by this source

70

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

2

Sponsor

Name of organization / entity

Goldaru Pharmaceutical Company

Full name of responsible person

Dr. Fariborz Moattar

Street address

plaque47.Safeh Industrial Estate.esfahan

City

Isfahan

Province

Isfahan

Postal code

81745/594

Phone

+98 31 3654 0122

Email

info@goldaru_co.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Goldaru Pharmaceutical Company

Proportion provided by this source

30

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

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Hamed Ghavimi

Position

academic member

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Next. MousaviHospital ,Gavazang Rd.

City

zanjan

Province

Zanjan

Postal code

4513956184

Phone

+98 24 3347 3635

Email

Hamed.ghavimi@gmail.com

zahra jafari

Position

pharmacy student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

Street address

Next. Mousavihospital . Gavazang Rd.

City

zanjan

Province

Zanjan

Postal code

4513956184

Phone

+98 24 3355 9972

Email

jafari.pharmacy@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Zanjan University of Medical Sciences

Full name of responsible person

Dr. hamed ghavimi

Position

academic member

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

next. mousavihospital, gavazang Rd

City

zanjan

Province

Zanjan

Postal code

4513956184

Phone

2433473635-7

Email

hamed.ghavimi@gmail.com

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

Zanjan University of Medical Sciences

Full name of responsible person**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Part of the data, such as information about the main outcome, can be shared.

When the data will become available and for how long

three months.

To whom data/document is available

Researchers.

Under which criteria data/document could be used

The person can access the data after requesting and verifying its reliability.

From where data/document is obtainable

Central Library of Medical Sciences University.

What processes are involved for a request to access data/document

The person can access the data after requesting and verifying its reliability.

Comments