

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Evaluation of prophylactic effect of Livergol (Silymarin) on liver function tests in patients with outpatient cancer undergoing chemotherapy: a randomized controlled clinical trial

#### Protocol summary

##### Study aim

Evaluation of the prophylactic effect of Livergol (Silymarin) on liver function tests in patients with outpatient cancer undergoing chemotherapy

##### Design

Clinical trials with control group with randomized, multifaceted, randomized, randomized groups

##### Settings and conduct

Evaluation of the effect of pharmacological intervention on the prevention of liver damage caused by chemotherapy in cancer patients referred to outpatient clinics affiliated to Isfahan University of Medical Sciences that have chemotherapy indications. Blinding of groups for clinicians, researchers and data analysts.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria include patients aged 30 to 60 years with the ability to take the drug orally with no pregnancy and lactation and a definite diagnosis of breast cancer who have chemotherapy indications and have not yet received their chemotherapy drug and liver tests are normal before intervention and without liver metastasis and disease.

##### Intervention groups

Daily administration of two 140 mg silymarin tablets one week before the start of the chemotherapy course in the intervention group 1 and two daily silymarin 140 mg tablets simultaneously with the start of the chemotherapy course in the intervention group 2 and placebo tablets in the control group

##### Main outcome variables

The main consequences are liver function variables including ALT, AST, BILIRUBIN, ALP tests.

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20201123049474N2**

Registration date: **2021-08-16, 1400/05/25**

Registration timing: **prospective**

Last update: **2021-08-16, 1400/05/25**

Update count: **0**

#### Registration date

2021-08-16, 1400/05/25

#### Registrant information

##### Name

Mohammad Amin

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3781 2884

##### Email address

dr.mohamad.amin@gmail.com

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2021-08-23, 1400/06/01

#### Expected recruitment end date

2022-08-23, 1401/06/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Evaluation of prophylactic effect of Livergol (Silymarin) on liver function tests in patients with outpatient cancer

undergoing chemotherapy: a randomized controlled clinical trial

### Public title

Evaluation of prophylactic effect of Livergol (Silymarin) on liver function tests in patients with outpatient cancer undergoing chemotherapy

### Purpose

Prevention

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Patients aged 30 to 60 years Ability to take the drug orally Definitive diagnosis of breast cancer that has chemotherapy indications and has not yet received its chemotherapy drug Liver tests are normal before the intervention Indication of treatment with chemotherapy regimen

#### Exclusion criteria:

pregnant and breastfeeding liver metastasis and liver disease

### Age

From **30 years** old to **60 years** old

### Gender

Both

### Phase

3

### Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

### Sample size

Target sample size: **105**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Randomization is done by the method of six balanced block randomization in such a way that in each block with different possibilities, there are two cases A, two cases B and two cases C. Each letter represents the study groups. Creating random values to be assigned to blocks is done in spss software. Then, an independent person from the research team encodes 105 envelopes (based on the codes obtained in the above randomization method) and determines the list of codes. The inside of the envelope will be written according to the above new treatment method or standard (conventional) treatment and in the order of eligible patients entering the clinic, patients will be given to give to the oncologist. The treating physician will prescribe and make the necessary recommendations for each patient based on the grouping performed. The researcher is also unaware of which group each patient is in.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

The secretary introduced the patients to the oncologist using a randomized grouping and the oncologist provided treatments for all groups according to the

grouping done. The investigator, in collaboration with the oncologist, supervised the patient's use of the drug. After collecting the laboratory data, the results were analyzed by a statistician specialist with respect to the confidentiality of the grouping.

### 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

Ethics committee of Isfahan medical university, Building No. 4, Isfahan medical university, Hezar Jarib Street, Isfahan

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

#### Approval date

2020-11-29, 1399/09/09

#### Ethics committee reference number

IR.MUI.MED.REC.1399.763

## Health conditions studied

### 1

#### Description of health condition studied

Chemotherapy induced liver injury

#### ICD-10 code

S36.11

#### ICD-10 code description

Injury of liver

## Primary outcomes

### 1

#### Description

liver function test

#### Timepoint

Measurement of liver enzymes at the beginning of the study (before the intervention) and 3 and 6 weeks after the start of silymarin

#### Method of measurement

Lab data

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: The first treatment group receives two 140 mg silymarin tablets one week before the start of the chemotherapy course and is taken daily for two months after the chemotherapy treatment.

#### Category

Prevention

### 2

#### Description

Intervention group: The second treatment group receives two 140 mg silymarin tablets from the start of the chemotherapy course and is taken daily for two months after chemotherapy.

#### Category

Prevention

### 3

#### Description

Control group: They receive two placebo tablets daily for two months from the time of chemotherapy

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Alzahra clinics

##### Full name of responsible person

Ali Hajigholami

##### Street address

Sheikh Mofid Street

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8163743787

##### Phone

+98 31 3663 1677

##### 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 Haghjooye Javaanmard

##### Street address

Hezar Jarib Street-Vice Chancellery of Research and Technology

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

##### Phone

+98 31 3668 8138

##### Email

sh\_haghjoo@med.mui.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Esfahan 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

Safoora Sadat Erfanian

##### Position

Resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Internal Medicine

##### Street address

Internal medicine department, Alzahra hospital, Softe Blvd, Shahid Keshvari High Way

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##### Province

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##### Postal code

8174675731

##### Phone

+98 31 3620 1991

##### Email

S.erfanian72@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Dr Houriyeh Ansari

**Position**

Specialist

**Latest degree**

Specialist

**Other areas of specialty/work**

Public Health/Community Medicine

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**Email**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Safoora Sadat Erfanian

**Position**

Resident

**Latest degree**

Medical doctor

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Internal Medicine

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**Phone**

+98 31 3620 1991

**Email**

S.erfanian72@gmail.com

## 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**

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**

All data in the study except for personal data can be shared.

**When the data will become available and for how long**

The start of the access period is 6 months after the results are printed.

**To whom data/document is available**

At the current stage, the results will be available to researchers at university institutes.

**Under which criteria data/document could be used**

In terms of data analysis and analysis for academic researchers and use in later studies.

**From where data/document is obtainable**

School of social medicine, Isfahan

Ali\_hajigholami@yahoo.com

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

By submitting a written request to the director of the Social Medicine School, Isfahan

**Comments**