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

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Iran (Islamic Republic of)

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+98 31 3781 2884

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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 was 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
Isfehan

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
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Sheikh Mofid Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjooye Javaanmard
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Hezar Jarib Street-Vice Chancellery of Research and Technology
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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
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
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Person responsible for updating data

Contact

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Position
Resident

Latest degree
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Other areas of specialty/work
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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