Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Evaluating the effect of silymarin oral form on the control of liver toxicity caused by AC regimn in patients with non metastatic breast cancer

Protocol summary

Summary

Forty patients with non-metastatic breast cancer treated with an adriamycin+cyclophosphamide regimen who have grade 2 hepatic toxicity based on NCI-CTC version4 randomly (according to a computerized list provided by randomization.com site) will assigned to one of two drug or placebo groups. Twenty patients in the drug group will receive Livergol tablets containing 140 mg of silymarin three times a day after each meal, and twenty patients in the placebo group will receive tablets similar in appearance to Livergol which contain non-active ingredients of the Livergol tablet. The liver function tests including hepatic transaminases, bilirubin (total and direct), albumin and alkaline phosphatase will be performed at the beginning of the study,after two weeks and at the end of the first month. Liver ultrasound will be done at the beginning of the study and after a month. Also, liver fibroscan will be done at the end of a month for a closer look. Then the liver status will be compared between the two groups of drugs and placebo.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017091136125N1**
Registration date: **2017-10-24, 1396/08/02**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-10-24, 1396/08/02

Registrant information

Name
Ghazal Saadat Askarpour Moezian
Name of organization / entity
Mashhad University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences Gol daroo Pharmaceutical Company, Isfahan, Iran

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2018-10-23, 1397/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of silymarin oral form on the control of liver toxicity caused by AC regimn in patients with non metastatic breast cancer

Public title

Evaluating the effect of silymarin oral form on the control of liver toxicity caused by adriamycin and cyclophosphamide drugs in patients with non metastatic breast cancer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Non-metastatic breast cancer that has undergone chemotherapy with cyclophosphamide + doxorubicin after mastectomy; Grade 2 or higher grade liver toxicity based on NCI-CTC version4 based on AST,

ALT or Bilirubin level that will be evaluated at the beginning of each chemotherapy course; Age between 18 to 65 years Exclusion criteria: Patients with viral hepatitis (A, B and C); hepatobiliary obstruction; history of hepatic or renal; malabsorbtion syndrome ; gastrointestinal obstruction ; patients dissatisfaction; co-administration of hepatotoxic medications; consumption of antioxidant medication; chemotherapy regimen modification

Age
From **18 years** old to **65 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences

Street address
Ghoreishi Building, Daneshgah Street, Mashhad, Iran

City
Mashhad

Postal code
1394491388

Approval date
2017-07-23, 1396/05/01

Ethics committee reference number
IR.MUMS.SP.1396.161

Health conditions studied

1

Description of health condition studied
Hepatotoxicity

ICD-10 code
K71.1

ICD-10 code description
Hepatotoxicity

Primary outcomes

1

Description
Serum level of hepatic transaminases, total billirubin, direct billirubin, prothrombin time, serum albumin, alkalin phosphatase

Timepoint
at the beginning of the study, 2 weeks afterthe beginning of study, one month after the begining of the study

Method of measurement
Serum level measurement by labratory

2

Description
Liver ultrasound to determine the stage of the fatty liver

Timepoint
at the beginning of the study, one month after the begining of the study

Method of measurement
Ultrasound

3

Description
Hepatic fibroscan

Timepoint
One month after the begining of the study

Method of measurement
Fibroscan

Secondary outcomes

1

Description
Serum level of creatinine and urea

Timepoint
At the beginning of the study, 2 weeks after the beginning of study, one month after the begining of the study

Method of measurement
Serum level measurementl by labratory

Intervention groups

1

Description
Intervention group: Livergol 140 mg three tablets daily after meals (produced by Goldaroo company), oral, for 4weeks

Category
Treatment - Drugs

2

Description
Control group : Placebo tablets for Livergol, three tablet daily after meals, for 4 week, oral
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Omid hospital, affiliated to Mashhad University of Medical Sicences
Full name of responsible person
Street address
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
Ghoreishi Building, Daneshgah Street, Mashhad, Iran
City
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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
Vice chancellor for research, Mashhad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Mashhad University of Medical Science, Faculty of Pharmacy
Full name of responsible person
Ghazal Saadat Askarpour Moezian
Position
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Person responsible for scientific inquiries

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Person responsible for updating data

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Fax

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty