

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3764 9222

###### Email address

asgarpourgh921@mums.ac.ir

###### 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; malabsorption 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 bilirubin, direct bilirubin, prothrombin time, serum albumin, alkaline phosphatase

**Timepoint**

at the beginning of the study, 2 weeks after the beginning of study, one month after the beginning of the study

**Method of measurement**

Serum level measurement by laboratory

**2****Description**

Liver ultrasound to determine the stage of the fatty liver

**Timepoint**

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

**Method of measurement**

Ultrasound

**3****Description**

Hepatic fibroscan

**Timepoint**

One month after the beginning 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 beginning of the study

**Method of measurement**

Serum level measurement by laboratory

**Intervention groups****1****Description**

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

**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 Sciences

##### 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

Mashhad

##### 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

PharmD student

#### Other areas of specialty/work

#### Street address

School of Pharmacy, Ferdowsi University campus, Vakil Abad Blvd., Mashhad

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#### Postal code

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+98 51 3882 3255

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asgarpourgh921@mums.ac.ir

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Mashhad University of Medical Sciences, Faculty of Pharmacy

#### Full name of responsible person

Sepideh Elyasi

#### Position

Assistant Professor

#### Other areas of specialty/work

#### Street address

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## Person responsible for updating data

### Contact

#### Name of organization / entity

Mashhad University of Medical Sciences, Faculty of Pharmacy

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Ghazal Saadat Askarpour Moezian

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PharmD student

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#### City

Mashhad

#### Postal code

#### Phone

00

#### Fax

**Email**  
**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*