

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### To evaluate the effectiveness of Silymarin (Livergol) on IL-6 levels and size of endometrioma lesions in women with ovarian endometriosis: a randomized, double-blind placebo-controlled trial

#### Protocol summary

##### Study aim

Evaluation and comparison of the effectiveness of silymarin tablet (Livergol) on size of endometrioma lesions and interleukin-6 level in women with ovarian endometriosis before and after intervention

##### Design

they are randomly divided into two groups: A (intervention group) and B (control group). The sample size required is pilot study of at least 10 patients in each group as a pilot study in Phase II of the clinical trial.

##### Settings and conduct

Gynecologists perform in hospitals and offices. For this purpose, Livergol tablets and placebo are coded by a research center. The lead researcher treats patients in a double-blind manner based on the drug package code. The code for the drug package is recorded on the personal information form and the researcher who completes the information form will not be informed of the type of treatment.

##### Participants/Inclusion and exclusion criteria

Iranian married women of reproductive age (15-49); with a confirmed diagnosis of ovarian endometriosis via transvaginal ultrasonography performed by a single sonologist and CA125 level; No chronic disease based on medical records; without taking specific medications or anti-inflammatory supplements with a specified wash-out period for each one

##### Intervention groups

All participants in the intervention group will receive a dose of 280 mg silymarin including two tablets of Livergol 140 mg, Goldaru Pharma Co. Isfahan-Iran) and women in the control group will receive placebo tablets (Goldaru Pharma Co. Isfahan-Iran) daily in two meals (after breakfast and dinner) for 12 weeks along with standard treatment of endometrioma (dienogest 2mg/day, NSAIDs, estrogen and progesterone). The therapeutic doses of silymarin have been considered

safe and well-tolerated in humans without any interaction with endometriosis treatment

##### Main outcome variables

the size of endometrioma lesions; Interleukin 6 levels

#### General information

##### Reason for update

Completion of the sampling process and statistical analysis led us to update the recorded information of different sections of this trial in IRCT. As we have believed that this study might hold enormous potential for improving promising therapeutic agents to benefit patients who are suffering from various manifestations of endometriosis, especially endometrioma. Unfortunately, while updating the information related to the actual recruitment start/end dates, we noticed an inadvertent error in recording the expected recruitment start and end dates of the sampling, and a need has been felt on the imperative for transparency, accountability in order to fix that error and explain its causes to re-establish researchers' trust in this clinical trial's accuracy and reliability. All available evidence, including the date of approval of this clinical trial in the ethics committee of Tarbiat Modares University (IR.MODARES.REC.1398.143) and the date of entry of the researcher to the master's degree (1397-98 academic year) indicate an inadvertent error in the registration of this study and make the possibility of conducting this study in that time (before registration) unfeasible. We take full responsibility for the situation and all of patients' consents and questionnaire forms with detailed for the current study are available upon any requests. In addition, the simultaneous recruiting of patients and the coronavirus pandemic and its lockdown resulted in study participants' inaccessibility and trial personnel for in-person scheduled study visits and/or follow-up led to prolong sampling process and its postponement.

##### Acronym

## IRCT registration information

IRCT registration number: **IRCT20150905023897N5**

Registration date: **2020-02-04, 1398/11/15**

Registration timing: **prospective**

Last update: **2022-02-23, 1400/12/04**

Update count: **2**

## Registration date

2020-02-04, 1398/11/15

## Registrant information

### Name

Dr. Shahideh Jahanian Sadatmahalleh

### Name of organization / entity

Tarbiat Modares University

### Country

Iran (Islamic Republic of)

### Phone

+98 21 8288 4826

### Email address

shahideh.jahanian@modares.ac.ir

## Recruitment status

**Recruitment complete**

## Funding source

## Expected recruitment start date

2020-02-07, 1398/11/18

## Expected recruitment end date

2021-03-14, 1399/12/24

## Actual recruitment start date

2020-03-02, 1398/12/12

## Actual recruitment end date

2021-05-18, 1400/02/28

## Trial completion date

2021-08-21, 1400/05/30

## Scientific title

To evaluate the effectiveness of Silymarin (Levergol) on IL-6 levels and size of endometrioma lesions in women with ovarian endometriosis: a randomized, double-blind placebo-controlled trial

## Public title

To evaluate the effectiveness of Silymarin (Levergol) on IL-6 levels and size of endometrioma lesions

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Iranian married women of reproductive age (15-49) No chronic disease (diabetes, hypertension, liver and kidney disease, previous venous embolism ...) based on medical records Women with a confirmed diagnosis of ovarian endometriosis via transvaginal ultrasonography performed by a single sonologist and CA125 level People are willing to participate in the study

### Exclusion criteria:

participants suffering from the side effects of silymarin Individuals unwilling to continue participating in the study Failure to comply with treatment protocol Taking specific medications such as anti-depressant, GnRH analogues, systemic glucocorticoids, or other milk thistle

products and anti-inflammatory supplements with a specified wash-out period for each one

## Age

From **15 years** old to **49 years** old

## Gender

Female

## Phase

2

## Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

## Sample size

Target sample size: **60**

Actual sample size reached: **70**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Simple randomization will be done according to a computer-generated list of random number groups prepared using Statistical Analysis System Software Version 9.2 (SAS Institute Inc., Cary, NC, USA). All participants will be randomly allocated to each arm and given the tablets based on a computer-generated randomization list by the investigator.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

The researcher and patients will be unaware of the treatment and grouping of the study. For this purpose, Levergol tablets and placebo are coded by a research center. The lead researcher treats patients in a double-blind manner based on the drug package code. The code for the drug package is recorded on the personal information form, and the researcher who completes the information form will not be informed of the type of treatment.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

1

### Ethics committee

#### Name of ethics committee

Ethics committee of Tarbiat Modares university

#### Street address

Jalal AleAhmad-Nasr, Tarbiat Modares University

#### City

Tehran  
**Province**  
Tehran  
**Postal code**  
11114115  
**Approval date**  
2019-10-22, 1398/07/30  
**Ethics committee reference number**  
IR.MODARES.REC.1398.143

## Health conditions studied

### 1

#### **Description of health condition studied**

Endometrioma lesions

#### **ICD-10 code**

N80.1

#### **ICD-10 code description**

Endometriosis of ovary

## Primary outcomes

### 1

#### **Description**

Interleukin 6 levels

#### **Timepoint**

At the beginning of the study and three months after starting the Livergol pill

#### **Method of measurement**

Using the ELISA method in pg / ml

### 2

#### **Description**

Endometrial lesion volume measurement

#### **Timepoint**

At the beginning of the study and three months after starting the Livergol pill

#### **Method of measurement**

ultrasound or laparoscopy in millimeters

### 3

#### **Description**

Sexual function

#### **Timepoint**

At the beginning of the study and three months after starting the Livergol pill

#### **Method of measurement**

Using the FSFI questionnaire

### 4

#### **Description**

Quality of Life

#### **Timepoint**

At the beginning of the study and three months after starting the Livergol pill

#### **Method of measurement**

Using the SF-12 questionnaire

### 5

#### **Description**

Pelvic pain

#### **Timepoint**

At the beginning of the study and three months after starting the Livergol pill

#### **Method of measurement**

VAS visual analog scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### **Description**

Intervention group: People in the intervention group receive Liverpool 140 mg tablets at the pharmaceutical company twice daily for three months.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: People in the control group used the placebo for exactly three months with exactly the same appearance of the Levergel tablet twice a day for three months.

#### **Category**

Treatment - Drugs

## Recruitment centers

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Arash hospital

##### **Full name of responsible person**

Shahideh Jahanian Sadatmahalleh

##### **Street address**

Alley 162, Shahid Baghdarnia Ave, after Shahid B, Resalat Highwayagheri Highway,

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Tehran

##### **Province**

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##### **Fax**

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##### **Email**

hosp\_arash@tums.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Vice chancellor for research Tarbiat Modares University

**Full name of responsible person**

Mohammad Javan

**Street address**

Jalal Al Ahmad Street, Iran

**City**

Tehran

**Province**

Tehran

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**Fax**

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**Email**

pres@modares.ac.ir

**Web page address****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 Tarbiat Modares University

**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**

Tarbiat modares University

**Full name of responsible person**

Shahideh Jahanian Sadatmahalleh

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

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### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

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**Latest degree**

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### Person responsible for updating data

**Contact****Name of organization / entity**

Tarbiat Modares University

**Full name of responsible person**

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**Position**

Assistant Professor

**Latest degree**

Ph.D.

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**Email**

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

No - There is not a plan to make this available

### Statistical Analysis Plan

No - There is not a plan to make this available

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

No - There is not a plan to make this available

### Analytic Code

No - There is not a plan to make this available

## Data Dictionary

No - There is not a plan to make this available

### Title and more details about the data/document

Information on the main outcome of the study

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

1400

### To whom data/document is available

Academic researchers

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

Use for further research in the future

### From where data/document is obtainable

Email Addressing Responsible for Study

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

Submit a request to study and follow up

### Comments