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 (Levergol) 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, 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.

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
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Name of organization / entity
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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 (Livergol) 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 (Livergol) 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
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Alley 162, Shahid Baghdarnia Ave, after Shahid B, Resalat Highwayagheri Highway,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research Tarbiat Modares University

Full name of responsible person
Mohammad Javan

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Email
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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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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