Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jun 2026

The effect of Agnugol on painful symptoms of endometriosis and quality of life: a randomized clinical trial

Protocol summary

Study aim
The effect of Agnugol on painful symptoms of endometriosis and quality of life

Design
a clinical trial with a control group، parallel groups، triple blind، randomized by block method، phase3، on70patients

Settings and conduct
The place of research in this study is a doctor's office specializing in gynecological diseases in Tabriz city. A written informed consent will be obtained and a questionnaire of painful menstrual symptoms and quality of life specific to patients with endometriosis will be completed before allocation into groups. Then, the participants will be randomized using a random block method with a block size of four and with an allocation ratio of 1:1 They will be assigned to two groups of intervention (recipient of Agnugol tablets) and control (recipient of placebo). Allocation sequence will be done by someone not involved in sampling and data collection. Agnugol and placebo tablets will be prepared by Gol Daru pharmaceutical company in a completely similar way. This study is a three -way blind trial in wich the researcher, the participant and the analyst will not know ehich group the person is in.

Participants/Inclusion and exclusion criteria
inclusion women with endometriosis women in the age range of 18-49 women married and sexually active woman exclusion taking anti-inflammatory and hormonal drugs allergy to medicinal plants of the lamiaceae suffering from digestive diseases

Intervention groups
For the intervention group, Agnugol tablet with a dose of3.2 – 4.8mg and for the control group, placebo with the same dose will be given twice a day for 8 weeks.

Main outcome variables
8 weeks after the start of the intervention, participants will complete again painful menstrual symptoms and quality of life specific to patients with endometriosis.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180404039187N11**
Registration date: **2023-07-29, 1402/05/07**
Registration timing: **registered_while_recruiting**

Last update: **2023-07-29, 1402/05/07**
Update count: **0**

Registration date
2023-07-29, 1402/05/07

Registrant information

Name
Elnaz Shaseb

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-21, 1402/02/01

Expected recruitment end date
2023-09-21, 1402/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of Agnugol on painful symptoms of endometriosis and quality of life: a randomized clinical trial

Public title

The effect of Agnugol on painful symptoms of endometriosis and quality of life

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women with endometriosis whose disease has been diagnosed based on clinical symptoms and imaging (sonography) as well as previous documented evidence of endometriosis. Women with symptomatic endometriosis. Women who are in the age range of 18-49 years. They have not taken anti-inflammatory or hormonal drugs in the last three months. Don't have endometrial hypoplasia or neoplasia. Women who are married and sexually active.

Exclusion criteria:

Women who are allergic to medicinal plants, especially the Lamiaceae family. Women suffering from gallstones, jaundice due to biliary obstruction and acute biliary colic. Women with digestive diseases. Women who suffer from inflammatory diseases or diseases associated with immune system defects such as rheumatoid arthritis, lupus, multiple sclerosis, etc.

Age

From **18 years** old to **49 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

The participants will be assigned to two groups of intervention (recipient of Agnugol tablets) and control (recipient of placebo) by random block method with the size of blocks of four and with allocation ratio of 1:1. Allocation sequence will be done by someone not involved in sampling and data collection. Arrangement of the randomization process: 1) Determining the volume of each block (quadruple blocks) 2) Preparing the list of the blocks and assigning a number to each of them AABB(1) ABAB(2) ABBA(3) BBAA(4) BABA(5) BAAB(6) 3) Choosing random numbers between 1 and 6 4) Defining the treatment assignment list For example: AABB(1)_BBAA(4)_ABAB(2)_BABA(5)

Blinding (investigator's opinion)

Triple blinded

Blinding description

This study is a three -way blind trial in which the researcher, the participant and the analyst will not know each group the person is in. The participant will be assigned to two intervention groups(recipients of Agnugol) and control groups(recipients of placebo). Allocation sequence will be done by someone not involved in sampling and data collection. to conceal the allocation, the drug and placebo will be numbered and packed in the same container and consecutively. At the researcher level, blindness will be done as the researcher give the medicine to patients on the basis of label A or B without knowing the nature of A, B and according to the randomized list. At the patient's level, blindness will be done as the patients do not know in which group (control or intervention group) they are in. At the analyst level, blindness will be done as analyst will analyze the data without knowing the intervention and control group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz university of medical sciences

Street address

Research and technology dept, central building No.2, third floor, tabriz university of medical sciences, golgasht St, tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2022-11-01, 1401/08/10

Ethics committee reference number

IR.TBZMED.REC.1401.696

Health conditions studied

1

Description of health condition studied

endometriosis

ICD-10 code

N74.8

ICD-10 code description

Female pelvic inflammatory disorders in other diseases classified elsewhere

Primary outcomes

1

Description
quality of life of endometriosis patients
Timepoint
before investigation and 8 weeks after investigation
Method of measurement
questionnaire 30-EHP

2

Description
symptoms of pelvic pain and gynecology
Timepoint
before investigation and 8 weeks after investigation
Method of measurement
questionnaire ENDOPAIN-4D

Secondary outcomes

1

Description
pain
Timepoint
the first 3 days of the next 3 menstrual cycles
Method of measurement
VAS ruler

Intervention groups

1

Description
Agnugol tablet recipient at a dose of 3.2-4.8 mg once a day for 8 weeks
Category
Treatment - Drugs

2

Description
placebo tablet recipient at the same dose and appearance once a day for eight weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Hospital
Full name of responsible person
Elnaz Shaseb
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Tabriz 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
Tabriz University of Medical Sciences
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Elnaz Shaseb
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assistant professor
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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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available