Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of propolis supplementation in reducing pain in patients with Endometriosis

Protocol summary

Study aim
Evaluation of the effect of propolis in reducing pain of endometriosis patients

Design
Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 40 endometriosis patients. For randomization, permutation block method was used using the site www.randomization.com.

Settings and conduct
The study group are outpatients who use the medicine at home for 4 months. Patients will be collected from Imam Reza Hospital (endometriosis clinic). This clinical trial has a parallel, blinded (patients and interventionists) and randomized control group. The VAS score of the patients is evaluated at the beginning and 4 months after taking the drug or Darnama, and a statistical comparison is made before and after the administration of the drug and between the intervention groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: having endometriosis with pain. Age between 20 to 45 years. BMI between 18.5 to 27.5. Treated with a standard progesterone-only regimen. Not using NSAIDs to reduce pain. Not using food supplements. Informed consent to participate in the study. Exclusion criteria: allergy to propolis. Suffering from physical and mental illnesses. Use of hormonal methods in the last 3 months. Pregnancy or breastfeeding in the last 3 months.

Intervention groups
Intervention group: Propolis tablets 500 mg twice a day for 4 months along with standard hormonal treatment. Control group: standard treatment (progesterone drugs) along with placebo tablets twice a day for 4 months..

Main outcome variables
Endometriosis pain based on visual analog scale (VAS)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20141230020486N5**
Registration date: **2023-10-14, 1402/07/22**
Registration timing: **prospective**

Last update: **2023-10-14, 1402/07/22**
Update count: **0**

Registration date
2023-10-14, 1402/07/22

Registrant information

Name
Leili Hafizi

Name of organization / entity
Mashhad University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-10-23, 1402/08/01

Expected recruitment end date
2024-05-21, 1403/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of propolis supplementation in reducing pain in patients with Endometriosis

Public title
Effect of propolis in pain of Endometriosis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patients with a definite diagnosis of endometriosis by imaging and have pain due to endometriosis Age between 20-45 years old Use of standard progesterone hormone treatments Not using NSAID medications Not refer for infertility treatment BMI between 18.5 to 27.5 Not taking food supplements Obtaining the patient's informed consent
Exclusion criteria:
Use of hormonal contraception and IUD during the last 3 months Pregnancy or breastfeeding in the last 3 months The presence of any physical and mental disease Drug sensitivity to propolis
Age
From **20 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked

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

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization is according to the block method with various block sizes. A random chain of two groups includes treatment (T) and control (C) with a ratio of 1:1 in blocks of size 4 and 6 (7 blocks of 4 and 2 blocks of 6) with the help of www.sealedenvelope.com for 40 volunteers. Also, a 4-digit personal ID is created for each volunteer. To hide the random allocation, boxes of the same shape are used for the drug and placebo, and these boxes correspond to the random sequence of T and C with the drug or placebo, the row number 1 to 40 and the ID code are recorded on it. The steps of preparation and arrangement of the random sequence are only at the disposal of the epidemiologist of the study. The number box placed is provided to the admissions officer of the applicants. When every candidate enters the study, the box corresponding to the candidate's number is provided to him.
Blinding (investigator's opinion)
Double blinded
Blinding description
All the study subjects, including the patients, the attending physician, and the project manager, are unaware of the allocation of patients to groups and the medicine they receive, and only the epidemiologist (responsible for randomization and final analysis of the data) is aware of the allocation method. The epidemiologist is neither involved in the prescription nor in the evaluation of the treatment and is only responsible for maintaining the codes and providing the numbered boxes containing the drug or placebo to the attending physician. On the boxes, only rows number 1 to 40 and the ID code are recorded, and the propolis or placebo tablets inside the box are exactly the same shape, size, and color. Therefore, it is not possible to identify the drug from the placebo for the patients, the attending physician, and the project manager. After taking the drug or placebo for 4 months, the patient is evaluated in the hospital clinic by the attending physician who does not know that he has received the drug or placebo and only knows about the ID code. Finally, the attending physician gives the evaluation results to the epidemiologist based on the code.
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
Vice Chancellor for Research and Technology, Third floor of Ghoreshi building, Next to Hoveyzeh Cinema, Daneshgah Street, Mashhad
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Mashhad
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Razavi Khorasan
Postal code
9138813944
Approval date
2023-05-22, 1402/03/01
Ethics committee reference number
IR.MUMS.IRH.REC.1402.061

Health conditions studied

1

Description of health condition studied
Endometriosis of pelvic peritoneum
ICD-10 code
N80.3
ICD-10 code description
Endometriosis of pelvic peritoneum

2

Description of health condition studied
Endometriosis of rectovaginal septum and vagina
ICD-10 code
N80.4
ICD-10 code description
Endometriosis of rectovaginal septum and vagina

Primary outcomes

1

Description
Endometriosis pain
Timepoint
Before the intervention and 4months after the intervention
Method of measurement
Visual Analogue Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: standard treatment (progesterone drugs) along with propolis tablets 500 mg twice a day for 4 months. These tablets are made by the pharmaceutical laboratory of the Mashhad Faculty of Pharmacy and look exactly like placebo tablets.
Category
Treatment - Drugs

2

Description
Control group: standard treatment (progesterone drugs) along with placebo tablets twice a day for 4 months. These tablets are made by the pharmaceutical laboratory of the Mashhad Faculty of Pharmacy and look exactly like propolis tablets.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Leili Hafizi
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Ibn Sina Street, Imam Reza Hospital Square, Imam Reza Educational Research and Treatment Center, Razavi Khorasan
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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
Mashhad 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
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Leili Hafizi
Position
Associate professor

Latest degree
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Person responsible for updating data

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is 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
Title and more details about the data/document
All data is potentially shareable after unidentifiable individuals
When the data will become available and for how long
Starting 6 months after publication
To whom data/document is available
People working in academic institutions
Under which criteria data/document could be used
Mention the source
From where data/document is obtainable
Dr. Lili Hafizi Email: hafizil@mums.ac.ir Phone: 09153107633
What processes are involved for a request to access data/document
Reply to email within a maximum of one week
Comments