

# 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](http://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

Lelli Hafizi

###### Name of organization / entity

Mashhad University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3802 2608

###### Email address

hafizil@mums.ac.ir

##### 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](http://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 Hoveyze Cinema, Daneshgah Street, Mashhad

**City**

Mashhad

**Province**

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

##### Street address

Ibn Sina Street, Imam Reza Hospital Square, Imam Reza Educational Research and Treatment Center, Razavi Khorasan

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9137913316

#### Phone

+98 51 3854 3031

#### Email

hafizil@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Majid Ghayour Mobarhan

##### Street address

Vice Chancellor for Research and Technology, third floor of Ghoreishi building, next to Hoveyze Cinema, University Street, Mashhad

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9138813944

##### Phone

+98 51 3841 1538

##### Email

GhayourM@mums.ac.ir

#### 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

Mashhad University of Medical Sciences

##### Full name of responsible person

Leili Hafizi

##### Position

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Ebnesima Street, Imam Reza Hospital, Gynecology Department

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913316

**Phone**

+98 51 3802 2608

**Fax**

+98 51 3852 5305

**Email**

hafizil@mums.ac.ir

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Emam Reza Sq, Ebne-sina Ave, Emam Reza hospital

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913316

**Phone**

+98 51 3802 2608

**Fax****Email**

hafizil@mums.ac.ir

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Leili Hafizi

**Position**

Associated professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Emam Reza Sq. Ebne-sina Ave, Emam Reza hospital

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913316

**Phone**

+98 51 3802 2608

**Fax****Email**

hafizil@mums.ac.ir

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Leili Hafizi

**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**