

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### Effect of combined vaginal cream (including honey, olive oil, and propolis) and oral contraceptive pill versus placebo with on treatment of functional cyst of ovary: a randomized clinical trial

#### Protocol summary

##### Study aim

To assess the effect of combined vaginal cream (including honey, olive oil, and propolis) and oral contraceptive pill versus placebo with on treatment of functional cyst of ovary

##### Design

This is a randomized clinical trial, phase III, in which 60 eligible patients will be randomly assigned to the intervention and control groups.

##### Settings and conduct

The eligible patients with cervicitis referring to the Health Centers in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 49 years, Functional cyst of ovary, Cyst of ovary less than 6 cm, Exclusion criteria: Pregnancy or breastfeeding, Complex ruptured cyst, Taking antibiotic or immunosuppressive medications to vaginal drugs in the past 2 weeks, Abnormal uterine bleedings, Liver, renal, hematologic, or central nerves system diseases or diabetes or immunodeficiency syndrome

##### Intervention groups

Intervention group 1: Combined vaginal cream (containing honey, olive, propolis) every night for 21 nights and after menstruation repeated for 21 nights  
Intervention group 2: Oral contraceptive pill every night for 21 nights and after menstruation repeated for 21 nights  
Control group: Receiving no treatment.

##### Main outcome variables

Primary outcome: Clinical symptoms, size of the ovarian cyst

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120215009014N384**

Registration date: **2021-02-16, 1399/11/28**

Registration timing: **prospective**

Last update: **2021-02-16, 1399/11/28**

Update count: **0**

##### Registration date

2021-02-16, 1399/11/28

##### Registrant information

##### Name

Jalal Poorolajal

##### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 1838 0090

##### Email address

poorolajal@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-02-19, 1399/12/01

##### Expected recruitment end date

2022-02-19, 1400/11/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Effect of combined vaginal cream (including honey, olive oil, and propolis) and oral contraceptive pill versus placebo with on treatment of functional cyst of ovary: a randomized clinical trial

**Public title**

Effect of combined vaginal cream (including honey, olive oil, and propolis) and oral contraceptive pill versus placebo with on treatment of functional cyst of ovary

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age of 18 to 49 years, Functional cyst of ovary, Cyst of ovary less than 6 cm,

**Exclusion criteria:**

Pregnancy or breastfeeding, Complex ruptured cyst, Taking antibiotic or immunosuppressive medications to vaginal drugs in the past 2 weeks, Abnormal uterine bleedings, Liver, renal, hematologic, or central nerves system diseases or diabetes or immunodeficiency syndrome

**Age**

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

**Gender**

Female

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare six sheets of paper, writing on two sheets the name of the intervention 1 and on two other sheets the name of the intervention 2 and on the third two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all six sheets are drawn. The six paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Hamadan University of Medical Sciences

**Street address**

Vice-chancellor for Research and Technology,  
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Approval date**

2020-12-29, 1399/10/09

**Ethics committee reference number**

IR.UMSHA.REC.1399.901

**Health conditions studied****1****Description of health condition studied**

Cyst of ovary

**ICD-10 code**

N83.0

**ICD-10 code description**

Follicular cyst of ovary

**Primary outcomes****1****Description**

Clinical symptoms

**Timepoint**

Before the intervention and 2 months later

**Method of measurement**

By taking history and clinical examination

**2****Description**

Size of the ovarian cyst

**Timepoint**

Before the intervention and 2 months later

**Method of measurement**

By ultrasonography

**Secondary outcomes**

empty

**Intervention groups**

## 1

### Description

Intervention group 1: Combined vaginal cream (containing honey, olive, propolis) every night for 21 nights and after menstruation repeated for 21 nights

### Category

Treatment - Drugs

## 2

### Description

Intervention group 2: Oral contraceptive pill every night for 21 nights and after menstruation repeated for 21 nights

### Category

Treatment - Drugs

## 3

### Description

Control group: Receiving no treatment.

### Category

N/A

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Health Centers in Hamadan city

#### Full name of responsible person

Arezoo Shayan

#### Street address

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

#### City

Hamadan

#### Province

Hamadan

#### Postal code

6517838695

#### Phone

+98 81 3838 0572

#### Email

arezoo.shayan2012@yahoo.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Hamedan University of Medical Sciences

#### Full name of responsible person

Dr. Saeid Bashirian

#### Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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#### Email

info.research@umsha.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

#### Full name of responsible person

Arezoo Shayan

#### Position

Master of Midwifery

#### Latest degree

Master

#### Other areas of specialty/work

Midwifery

#### Street address

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Hamedan University of Medical Sciences

#### Full name of responsible person

Dr. Zahra Masoomi

#### Position

Reproductive Health Specialist

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Reproductive Health

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zahramid2001@yahoo.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Jalal Poorolajal

**Position**

Professor of Epidemiology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Epidemiology

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**Province**

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**Email**

poorolajal@umsha.ac.ir

## 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