

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 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)

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+98 81 1838 0090

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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.

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6517838695

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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

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Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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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

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

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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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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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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