

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of treatment with metformin and metformin together with oral royal jelly on induction-ovulation cycles in infertile women with polycystic ovary syndrome.

Protocol summary

Study aim

Determining the effect of royal jelly on ovarian follicle size and maturation Determination of the effect of royal jelly on the thickness of the endometrium

Design

clinical trial , parallel-group, double-blind, randomized clinical trial, phase one, on 110 infertile women with polycystic ovary syndrome. two groups by random allocation. randomly assigned to one of groups A or B before entering the study. After the visit and receiving the prescription, they are referred to the desired pharmacy and receive one of the packs A or B, which includes metformin + royal gel capsules, and the other pack includes metformin and placebo capsules. In this way, patients are not deprived of the main treatment and do not know about the complementary treatment.

Settings and conduct

Sabzevar University of Medical Sciences Polycystic patients referred to the infertility clinic who are also subjected to ultrasound in the clinic

Participants/Inclusion and exclusion criteria

first be diagnosed with polycystic ovary syndrome using the Rotterdam criteria. Also, they should have a normal hysterosalpingography and the spouse's spermogram should be normal, and they should not have undergone ovulation induction

Intervention groups

. In the control group, metformin tablets 1500 mg + placebo capsules with the same color and shape as royal jelly are prescribed daily for two months, and in the experimental group, metformin tablets with the same dose and at the same time, plus royal gel with a dose of 800 mg are prescribed. It is given daily before breakfast. After taking the drugs for two months, both groups will be subjected to ovulation induction with Letrozole and CinalF,

Main outcome variables

Number of follicles, follicle size, endometrial thickness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220401054383N1**

Registration date: **2023-05-01, 1402/02/11**

Registration timing: **registered_while_recruiting**

Last update: **2023-05-01, 1402/02/11**

Update count: **0**

Registration date

2023-05-01, 1402/02/11

Registrant information

Name

mehri sakhdari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4261 6208

Email address

mehri.sakhdari@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-31, 1401/03/10

Expected recruitment end date

2023-08-21, 1402/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of treatment with metformin and metformin together with oral royal jelly on induction-ovulation cycles in infertile women with polycystic ovary syndrome.

Public title

The effect of Royal jelly on ovulation induction cycles in infertile women with polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Polycystic ovary syndrome has been confirmed using the Rotterdam criteria normal hystrosalpyngography Husband's spermogram should be normal Have not been subjected to ovulation induction have completed the informed consent form to participate in the research

Exclusion criteria:

Any medication for induction dissatisfaction Non-confirmation of polycystic ovary syndrome using the Rotterdam criteria

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

1-2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

In this research, the allocation of samples to each group is done in a simple random manner, so that after confirming the inclusion criteria, we place the first person in the intervention or control group with a simple randomization model of lion or line by tossing a coin. (line in the intervention group and milk in the control group) and after that they will be placed in the middle of the intervention and control groups until the number of samples in the two groups is completed.

Blinding (investigator's opinion)

Double blinded

Blinding description

The method of blinding in this study will be that before entering the study, eligible patients will be randomly assigned to one of groups A or B, and the demographic information of the desired group will be recorded in the questionnaire. After the visit and receiving the prescription, they are referred to the desired pharmacy and receive one of the packs A or B, which includes metformin + royal gel capsules, and the other pack

includes metformin and placebo capsules. In this way, patients are not deprived of the main treatment and do not know about the complementary treatment. The researcher also does not know about the content of the pills, and only in this research is the knowledgeable person a pharmaceutical consultant.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Sabzevar University of Medical Sciences

Street address

North Kashfi St

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617913114

Approval date

2022-03-14, 1400/12/23

Ethics committee reference number

IR.MEDSAB.REC.1400.188

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

Polycystic ovarian syndrome +infertility

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

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

the size of the follicles:the size of one or more follicles has reached 18-22 mm

Timepoint

Examination at the beginning of the study and after 8 weeks of receiving the drug

Method of measurement

Transvaginal ultrasound , positive pregnancy test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: We will give 55 members of the intervention group, who were randomly selected, one 1000 mlroyal gel capsule daily for 8 weeks along with other induction ovulation drugs. The capsules are prepared online from Positive Sabz Pharmacy and belong to the brand: OPD Pharma with product ID: 885595 and imported barcode: 6262248103293.

Category

Treatment - Drugs

2

Description

Control group: Members of the control group only receive ovulation induction drugs and metformin

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mobini Hospital Clinic and Dr. Behnaz Soizi 's office
(The supervisor of dissertation))

Full name of responsible person

Mehri Sakhdari

Street address

North Kashfi St

City

Sabzevar

Province

Razavi Khorasan

Postal code

9613856776

Phone

+98 51 4423 8100

Fax

+98 51 4422 1002

Email

Mobini.h@medsab.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellor's Office for Research of Sabzevar
university

Full name of responsible person

Mohammadhosein Saghi

Street address

North Kashfi St

City

Sabzevar

Province

Razavi Khorasan

Postal code

9613856776

Phone

+98 51 4423 8100

Email

Mobini.h@medsab.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-Chancellor's Office for Research of Sabzevar
university

Proportion provided by this source

50

Public or private sector

Private

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

Sabzevar University of Medical Sciences

Full name of responsible person

Mehri Sakhdari

Position

Gynecologist

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

North Kashfi St

City

Sabzevar

Province

Razavi Khorasan

Postal code

9613856776

Phone

+98 51 4423 8100

Email

Mobini.h@medsab.ac.ir

Person responsible for scientific

inquiries

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Mehri Sakhdari

Position

Gynecologist

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

No. 204, Fazal St

City

Nishaboor

Province

Razavi Khorasan

Postal code

9318788571

Phone

+98 51 4261 6208

Email

mehri.sakhdari@yahoo.com

Postal code

9318788571

Phone

+98 51 4261 6208

Email

Mehri.sakhdari@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

The results of the data will be published in the form of articles and the information of the participants will remain confidential.

When the data will become available and for how long

The beginning of 1400 and the end of 1402

To whom data/document is available

Accessible to the public

Under which criteria data/document could be used

Fisher's chi-square and Mann-Whitney statistical tests and..

From where data/document is obtainable

Can be published on official sites

What processes are involved for a request to access data/document

After the defense in the faculty, it will be published as an article

Comments

Person responsible for updating data

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Mehri Sakhdari

Position

Gynecologist

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

No. 204, Fazal St

City

Nishaboor

Province

Razavi Khorasan