Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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 demo graphic 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 pegs, 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

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice-Chancellor's Office for Research of Sabzevar univercity

Full name of responsible person
Mohammadhosein Saghi

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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
Vice-Chancellor's Office for Research of Sabzevar univercity

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
Gynecologyst

Latest degree
Medical doctor

Other areas of specialty/work
Gynecology and Obstetrics

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inquiries

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Latest degree
Medical doctor

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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