

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Investigating the effect of jujube hydroalcoholic extract on the pregnancy outcomes of infertile polycystic ovary syndrome patients s undergoing ovulation induction and comparing it with myoinositol and metformin.

Protocol summary

Study aim

To determine the effect of jujube hydroalcoholic extract on the pregnancy outcome of polycystic ovary syndrome patients undergoing ovulation induction.

Design

Double-blind randomized clinical trial

Settings and conduct

This clinical trial will be conducted in Imam Reza Hospital (AS) Mashhad (Milad Infertility Center) and infertility clinics in Mashhad city. Polycystic ovary and infertility patients who, according to the infertility specialist, should undergo ovulation induction with letrozole, are placed in the metformin, myinositol, jujube and placebo group for 12 weeks as a pre-treatment. Clinical and biochemical fertility results will be reported and compared after this period and the use of letrozole by all patients. Anthropometric indicators, lipid profile, sugar profile and clinical symptoms of polycystic ovary patients will be investigated at the beginning and end of the intervention.

Participants/Inclusion and exclusion criteria

Women with PCOS according to the Rotterdam criteria in the age range of 18-45 years Willingness to cooperate in the project Trying to get pregnant for more than a year - No history of liver and kidney disease No other metabolic diseases - No history of hyperprolactinemia, Cushing's, hypothyroidism, congenital adrenal hyperplasia - Absence of various allergies - Not using contraceptive and hormonal pills during the 3 months before the study

Intervention groups

Patients with polycystic ovary syndrome and infertility

Main outcome variables

biochemical pregnancy clinical pregnancy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230712058752N1**

Registration date: **2023-07-18, 1402/04/27**

Registration timing: **registered_while_recruiting**

Last update: **2023-07-18, 1402/04/27**

Update count: **0**

Registration date

2023-07-18, 1402/04/27

Registrant information

Name

Faezeh Mashhadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3845 6274

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-12, 1402/04/21

Expected recruitment end date

2024-02-19, 1402/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of jujube hydroalcoholic extract

on the pregnancy outcomes of infertile polycystic ovary syndrome patients s undergoing ovulation induction and comparing it with myoinositol and metformin.

Public title
Investigating the effect of jujube hydroalcoholic extract on the pregnancy outcomes of infertile polycystic ovary syndrome patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Women with PCOS according to the Rotterdam criteria age range between18-45 years Willing to cooperate in the study Trying to get pregnant for more than a year No history of liver and kidney disease No other metabolic diseases No history of hyperprolactinemia, Cushing's, hypothyroidism, congenital adrenal hyperplasia Absence of various allergies Not using contraceptive and hormonal pills during the 3 months before the study
Exclusion criteria:
other metabolic disease thyroid disorders OCP and hormonal drugs before intervention history of allergy history of cancer alcohol or drugs abuse infertility due to disease another than PCOS

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
1-2

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **196**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation will be done using Sealedenvelope.com website. Blocks of 4 or 8 will be used to create a random sequence in the present study

Blinding (investigator's opinion)
Double blinded

Blinding description
In the groups receiving tablets, sachets and in the groups receiving sachets, placebo tablets will be used

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad Medical University of Medical Sciences, faculty of medicine
Street address
Mashhad, 91778 99191Razavi Khorasan Province
City
Mashhad
Province
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Postal code
۱۳۹۴۴ ۹۱۳۸۸
Approval date
2023-06-20, 1402/03/30
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1402.191

Health conditions studied

1

Description of health condition studied
polycystic ovary syndrome
ICD-10 code
N97.0
ICD-10 code description
Female infertility associated with anovulation

Primary outcomes

1

Description
biochemical pregnancy
Timepoint
after intervention
Method of measurement
blood sample

Secondary outcomes

1

Description
change in PCOS morphology in sonography
Timepoint
after intervention
Method of measurement
ultrasound sonography

Intervention groups

1

Description
the first Intervention group:: Jujube, in the form of jujube hydroalcoholic extract in the amount of one 10 gram sachet per day, dissolved in 100 cc of cooled boiled water and consumed by patients for 12 weeks. This sachet is prepared from jujube hydroalcoholic extract in

Mashhad Faculty of Medicine, Department of
Pharmacology
Category
Treatment - Drugs

2

Description
the second intervention group: Metformin, taking one
Glucophage 500 mg metformin tablet after lunch for 12
weeks
Category
Treatment - Drugs

3

Description
the third intervention group: Myoinositol, in the form of
one inofolic sachet daily for 12 weeks
Category
Treatment - Drugs

4

Description
Control group: Placebo, in tablet form in the sachet
receiving groups, and in sachet form in the pill receiving
groups, one daily for 12 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
milad infertility treatmaent center Imam Reza
Hospital Mashhad
Full name of responsible person
Faezeh Mashhadi
Street address
Mashhad, Imam Reza square, Imam Reza Hospital,
Milad infertility treatment center
City
Mashhad
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+98 51 3841 2081
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masshadif4001@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
Mashhad, Daneshgah street, Ghoreyshi departement
City
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Razavi Khorasan
Postal code
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+98 51 3841 1538
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mashhadif4001@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
Faezeh Mashhadi
Position
PhD student
Latest degree
Medical doctor
Other areas of specialty/work
Nutrition
Street address
Park square, mashhad university of medical sciences
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Person responsible for scientific

inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Faezeh Mashhadi

Position

Phd student

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Position

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Latest degree

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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

Yes - There is 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

Data related to blood tests and demographic factors of people will be published in the article after the study

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Researchers and people who are engaged in the pharmaceutical industry and market

Under which criteria data/document could be used

To investigate treatments that help to treat infertility

From where data/document is obtainable

Faezeh Mashhadi MD.PhD of nutrition science
mashhadif4001@mums.ac.ir

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

The reason for the need to send the data and the design proposal After review by the research team of the article and obtaining permission from them, the data will be available to the researcher

Comments