

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Comparison of the Impact of Calcitropin and Metformin as Adjunctive Therapy in Treating infertility in Women with Polycystic Ovary Syndrome

Protocol summary

Study aim

Treatment of infertility in women with polycystic ovaries (PCOS) with the herbal medicine of calcitropin

Design

Clinical trial with control group, parallel groups, triple-blind, random groups

Settings and conduct

In the infertility ward at the Alavi Hospital, via triple blind and random sampling

Participants/Inclusion and exclusion criteria

Women aged 20-45 years, i.e., first pregnancy, oliguria or menstrual disorders, clinical signs such as hyperandrogenism, no history of drug use for menstrual disorders in the last three months without any signs of infertility and no male factor in the partner Also, no history of neurological diseases. In case the above criteria are absent, the sample will be removed from the study.

Intervention groups

Metformin

Main outcome variables

Infertility treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140422017388N3**

Registration date: **2020-09-22, 1399/07/01**

Registration timing: **retrospective**

Last update: **2020-09-22, 1399/07/01**

Update count: **0**

Registration date

2020-09-22, 1399/07/01

Registrant information

Name

Sousan Houshmandi

Name of organization / entity

Ardebil University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 45 3351 2006

Email address

s.houshmandi@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2019-10-22, 1398/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Impact of Calcitropin and Metformin as Adjunctive Therapy in Treating infertility in Women with Polycystic Ovary Syndrome

Public title

Comparison of the Impact of Metformin and Calcitropin in Treating Polycystic Ovaries in Infertile Women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women aged 20-45 years i.e., first pregnancy, oliguria or menstrual disorders, clinical signs such as hyperandrogenism, no history of drug use for menstrual disorders in the last three months without any signs of

infertility No male factor in the partner

Exclusion criteria:

Absence of inclusion criteria

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

The main researcher, health caregivers, people charged with data collection

Placebo

Not used

Assignment

Parallel

Other design features

80

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ardabil University of Medical Sciences

Street address

Daneshgah St., Ardabil University of Medical Sciences, Ardabil

City

Ardabil

Province

Ardabil

Postal code

56189-53141

Approval date

2018-11-25, 1397/09/04

Ethics committee reference number

IR.RUMS.1397.142

Health conditions studied

1

Description of health condition studied

Polycystic ovaries, infertility

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

2

Description of health condition studied

Infertility

ICD-10 code

N97.9

ICD-10 code description

Female infertility, unspecified

Primary outcomes

1

Description

Infertile women with polycystic ovaries

Timepoint

Three months after taking the drug

Method of measurement

Sonography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Calcitrapin - People with polycystic ovary syndrome who have the inclusion criteria are placed in the intervention group and receive calcitrapin every twelve hours for three months, then after three months, they undergo ovulation induction of intrauterine insemination

Category

Other

2

Description

Control group: Ovulation induction: In the control group, people undergo metformin treatment for three months, then after this interval, they are placed under ovulation induction and intrauterine insemination. After two weeks, pregnancy tests are taken from both groups.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Alavi Hospital

Full name of responsible person

Sousan Houshmandi

Street addressDaneshgah St., After Shurabil Lake - Ardabil
University of Medical Sciences, Education and
Research Deputy**City**

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sousan2020@gmail.com

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Sousan Houshmandi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street addressAyatollah Moghaddas Ardabili Ave., Shahid Maadi St.,
Alavi Educational and Medical Center, Ardabil**City**

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Hakim Razi azar

Full name of responsible person

Habib Doshman Fekan

Street addressn the 25th km of the old Tehran Rd, Saeed Abad
village, Hakim Razi Azar company, East Azerbaijan**City**

Tabriz

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East Azarbaijan

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info@merspharma.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Hakim Razi azar

Proportion provided by this source

100

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**

Industry

Person responsible for general inquiries**Contact****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Ardabil University of Medical Sciences

Full name of responsible person

Sousan Houshmandi

Position

Faculty

Latest degree

Master

Other areas of specialty/work

Gynecology and Obstetrics

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Ardabil University of Medical Sciences

Full name of responsible person

Sousan Houshmandi

Position

Master of Science Midwife

Latest degree

Master

Other areas of specialty/work

Midwifery

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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