

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the Efficacy of Metformin and Inofolic in Ovulation induction in Patients with resistant Polycystic Ovarian Syndrome

Protocol summary

Study aim

Comparison of the efficacy of metformin and inofolic in ovulation induction in patients with resistant polycystic ovarian syndrome

Design

Randomized clinical trial without control group, with parallel groups, without blinding, phase 2 on 40 patients (a random numbers table used for allocation). This table contains the numbers 0 to 9 with the probability of occurrence being approximately equal. Random allocation concealment was performed by computer.

Settings and conduct

This study was conducted on 40 patients with PCOS based on Rotterdam criteria (including two of three following criteria: anovulation, clinical or biochemical signs of hyperandrogenic, polycystic ovaries in ultrasound), that referred to the Infertility Clinic of Imam Khomeini Hospital in Ahvaz.

Participants/Inclusion and exclusion criteria

Inclusion criteria: including oligomenorrhea, amenorrhea, evidence of polycystic ovaries on ultrasound, hyperandrogenism with or without obesity. Exclusion criteria: Lack of patient cooperation and inability to follow treatment for 3 months.

Intervention groups

Patients were randomly assigned to two groups of metformin (receiving 1 tablet of 500 mg twice daily) and inofolic (receiving 1 sochet twice a day, half an hour before breakfast and half an hour before dinner). Treatment was continued for 3 months

Main outcome variables

The primary outcome was comparison of follicular growth in both groups. Comparing the occurrence of biochemical pregnancy and also the number of dominant follicles was also compared between the groups as a secondary outcome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200816048427N1**

Registration date: **2020-10-15, 1399/07/24**

Registration timing: **retrospective**

Last update: **2020-10-15, 1399/07/24**

Update count: **0**

Registration date

2020-10-15, 1399/07/24

Registrant information

Name

Razieh Ghanbarzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3624 1035

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2018-10-23, 1397/08/01

Actual recruitment start date

2018-04-21, 1397/02/01

Actual recruitment end date

2018-10-23, 1397/08/01

Trial completion date

2018-10-23, 1397/08/01

Scientific title

Comparison of the Efficacy of Metformin and Inofolic in Ovulation induction in Patients with resistant Polycystic Ovarian Syndrome

Public title

Comparison of the Efficacy of Metformin and Inofolic in Ovulation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Presence of Oligomenorrhoea Presence of Amenorrhoea
Presence of Polycysticovarian Evidence in Ultrasound
Hypergonadism Lack of Response to Ovulation Induction
Therapy

Exclusion criteria:

Lack of patient cooperation Inability to follow treatment
for 3 months.

Age

From **22 years** old to **32 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization method, numbering of all samples starting from 01 to 40, then first 20 people selected using random numbers table are allocated to intervention A and the rest to intervention B. The researcher must first preset the direction for reading the table numbers (for example, up, down, left or right) then the researcher touches one of the numbers and moves in one of the predefined directions and records the numbers. And assigns to group A. The rest are assigned to Group B.

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 Ahvaz Jondishapur University of

Medical Sciences

Street address

Ekhlas 6 Ave, Jahadgaran Alley

City

Dorud

Province

Lorestan

Postal code

۶۸۸۱۷۹۴۶۷۱

Approval date

2018-11-17, 1397/08/26

Ethics committee reference number

IR.AJUMS.REC.1397.615

Health conditions studied

1

Description of health condition studied

polycystic ovarian syndrome(PCOS)

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes

1

Description

follicular growth

Timepoint

The size of the follicles at the beginning of treatment (before the intervention) and 90 days after the start of metformin and inofolic

Method of measurement

transvaginal ultrasonography

Secondary outcomes

1

Description

number of dominant follicles

Timepoint

At the beginning of the study (before the intervention) and 90 days after the start of metformin and inofolic

Method of measurement

transvaginal ultrasonography

Intervention groups

1

Description

First Intervention group: group of metformin (receiving 1 tablet of 500 mg twice daily)

Category

Treatment - Drugs

2

Description

Second Intervention group: group of inofolic (receiving 1 sochet twice a day, half an hour before breakfast and half an hour before dinner)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Medical Center of Ahvaz

Full name of responsible person

Razieh Ghanbarzadeh

Street address

Azadegan Ave., Imam Khomeini Medical Center, Ahvaz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

No

Title of funding source

Ahvaz Jundishapur University of Medical Sciences

Proportion provided by this source

70

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

Ahvaz University of Medical Sciences

Full name of responsible person

Razieh Ghanbarzadeh

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Resident

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Ekhlās 6 Ave, Jahadgaran Alley
City

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available