Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Adding Metformin to Clomiphen to improve ovulation rate in Clomiphen resistant women with polycystic ovarian syndrome: A randomized clinical trial study

Protocol summary

Summary

The aim of this study is to compare the effectiveness of adding Metformin to Clomiphen Citrate in women with polycystic ovarian syndrome (PCOS) to improve ovulation. This multicenter single-blind randomized controlled trial study was performed on 334 PCOS patients in Babol, Iran. Patients were divided in two groups randomly and ovulation induction was done with Clomiphen Citrate (CC) 50mg 2/day in both groups and the combination of CC and Metformin 500mg 3/day in intervention group. Number of mature follicle and pregnancy rate and number of patients who had dominant follicle were evaluated in each group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138904174306N1**
Registration date: **2010-08-24, 1389/06/02**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-08-24, 1389/06/02

Registrant information

Name

Masoumeh Golsorkhtabar Amiri

Name of organization / entity

Fatemeh-Zahra infertility and Reproductive Health Research center, Babol University of Medical Scien

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research and Technology of Babol University of Medical Sciences

Expected recruitment start date

2007-01-01, 1385/10/11

Expected recruitment end date

2009-01-01, 1387/10/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Adding Metformin to Clomiphen to improve ovulation rate in Clomiphen resistant women with polycystic ovarian syndrome: A randomized clinical trial study

Public title

Does ovulation rate improve in Clomiphen resistant women with polycystic ovarian syndrome by adding Metformin to Clomiphen?

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1. Infertile patients with PCOS. 2. Normal values of TSH and prolactin 3. Normal creatinin level 4. Normal liver function (SGOT, SGPT). Exclusion criteria: 1. hyperprolactinemia 2. thyroid disease 3.endometriosis 4. tubal factor 5. male factor 6. metformin with side effect background 7. diabetes mellitus.

Age

From **20 years** old to **35 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **334**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Vice chanceller for Research and Technology of Babol University of medical sciences

Street address
Gangafrooz St.

City
Babol

Postal code
47135-547

Approval date
2008-02-27, 1386/12/08

Ethics committee reference number
30/1/9056

Health conditions studied

1

Description of health condition studied
Polycystic ovarian syndrom

ICD-10 code
N97.0

ICD-10 code description
Female infertility associated with anovulation

Primary outcomes

1

Description
Number of mature follicle

Timepoint
12th-16th day of cycle

Method of measurement
transvaginal ultrasound

Secondary outcomes

1

Description
Pregnancy

Timepoint
16 days after IUI (16-18 cycle day)

Method of measurement
BHCG Examination

Intervention groups

1

Description
Clomiphen 50 mg, 2 per day, 5-7 days

Category
Treatment - Drugs

2

Description
Tab Metformin 500 mg, 3 per day, 3 month + Clomiphen 50 mg, 2 per day, 5-7 days

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Fatemeh-Zahra Infertility and Reproductive Health Research Center

Full name of responsible person
Dr. Zahra Basirat

Street address
Torkmahalleh - after Mohamad Hassan khan bridge

City
Babol

2

Recruitment center

Name of recruitment center
Mehrgan hospital, Infertility center

Full name of responsible person

Street address

City
Babol

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chanceller of Research and Technology of Babol University of medical sciences
Full name of responsible person
Dr. Amrollah Mostafazadeh
Street address
Gang afrooz avenue
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Babol
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chanceller of Research and Technology of Babol University of medical sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty