

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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)

Phone

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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 chancellor 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 chancellor of Research and Technology of Babol
University of medical sciences

Full name of responsible person

Dr. Amrollah Mostafazadeh

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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 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

Fatemeh-Zahra Infertility and Reproductive Health
Research Center, Babol University of Medical Sciences

Full name of responsible person

Masoumeh Golsorkhtabar Amiri

Position

BS.c

Other areas of specialty/work

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Person responsible for scientific inquiries

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Web page address

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