

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Clomiphen citrate versus metformin as first line approach for the treatment of anovulation in infertile patients with Polycystic Ovarian Syndrome

Protocol summary

Summary

Polycystic Ovarian Syndrome (PCO) is one of the most common causes of infertility due to anovulation. Clomiphene citrate (Clomid) and Metformin are categorized as ovulation induction drugs in these patients. In the present study, the effect of Clomid and Metformin is compared in the treatment of infertility in PCO patients. In a randomized controlled clinical trial, 104 infertile PCO patients with anovulation referred to infertility clinic of Bushehr University of Medical Sciences during 2010-2011 were studied in two equal groups. Informed written consent was obtained from all patients. For patients, Clomid was prescribed from the third day of menstruation for five days with 100mg per day or metformin was started with one tablet per day and was increased to two and three tablets. Ovulation was evaluated by ultrasonography at 13th-14th and measurement of serum progesterone in 21th day and pregnancy was confirmed by β HCG.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106236871N1**

Registration date: **2011-11-09, 1390/08/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-11-09, 1390/08/18

Registrant information

Name

Shahnaz Ahmadi

Name of organization / entity

Bushehr University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Bushehr University of Medical Sciences

Expected recruitment start date

2010-09-23, 1389/07/01

Expected recruitment end date

2011-07-11, 1390/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clomiphen citrate versus metformin as first line approach for the treatment of anovulation in infertile patients with Polycystic Ovarian Syndrome

Public title

Selecting optimized method for ovulation induction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Infertile anovulating PCO women in reproductive age of 18-30 and BMI of 19-25. Exclusion criteria: Any abnormality in thyroid and prolactin tests; structural abnormalities of uterus and tubes; metabolic disorders; cardiac and liver disease; cushing disease and

OCP users.

Age

From **18 years** old to **30 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **104**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Vice chancellor for research, Bushehr University of Medical Sciences

Street address

Paradise site of Bushehr University of Medical Sciences, Rishahr street, Bahmani

City

Bushehr

Postal code

Approval date

2011-04-28, 1390/02/08

Ethics committee reference number

20/18/3/4299/پ

Health conditions studied

1

Description of health condition studied

infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

pregnancy

Timepoint

14 days after ovulation

Method of measurement

βhCG Test

2

Description

Adequate follicle (16-22mm)

Timepoint

13th - 14th day of menstruation cycle

Method of measurement

Vaginal sonography

3

Description

Serum progesteron level

Timepoint

The 21th day of menstruation cycle

Method of measurement

Biochemical methods for measuring progesteron titer

4

Description

Alive fetus

Timepoint

The 7th week of pregnancy

Method of measurement

Vaginal sonography

Secondary outcomes

1

Description

Multiple pregnancy

Timepoint

7th week

Method of measurement

Ultrasonography

Intervention groups

1

Description

First group: Metformin will be started at 500mg daily and increased to maximum dose of 1500 mg daily during 3 weeks.

Category

Treatment - Drugs

2

Description

Second group: clomiphene citrate 100 mg orally for 5 days since 3rd day of menstruation cycle.

Category

Treatment - Drugs

Type of organization providing the funding*empty***Recruitment centers****1****Recruitment center****Name of recruitment center**

The outpatient clinic of Bushehr University of Medical Sciences

Full name of responsible person

Dr. Shahnaz Ahmadi

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Medical Faculty, Bushehr University of Medical Sciences, Moallem street

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2**Recruitment center****Name of recruitment center**

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

Vice chancellor for research, Bushehr University of Medical Sciences

Full name of responsible person

Dr Maryam Ravanipoor

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Bahmani

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Booshehr

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

Yes

Title of funding source

Vice chancellor for research, Bushehr 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****Person responsible for general inquiries****Contact****Name of organization / entity**

Bushehr University of Medical Sciences, Medical Faculty

Full name of responsible person

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assistant professor of clinical obstetrics and gynecology

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Medical Student

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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