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 pationts. In the present study, the effect of Clomid and Metformin is compared in the treatment of infertility in PCO pationts. 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 measurment of serum progestron in 21th day and pregnancy was confirmed by ßHCG.

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, Rishehr 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
ßhCG Test

2

Description
Adequate follicle (16-22mm)

Timepoint
13th - 14th day of mensturation cycle

Method of measurement
Vaginal sonography

3

Description
Serum progestron level

Timepoint
The 21th day of mensturation cycle

Method of measurement
Biochemical methods for measuring progestron 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
Ultasonography

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

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
Street address
Medical Faculty, Bushehr University of Medical Sciences, Moallem street
City
Bushehr

2

Recruitment center
Name of recruitment center
The outpatient clinic of Bushehr
Full name of responsible person
Dr. Shahnaz Ahmadi
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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
Street address
Bahmani
City
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
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Bushehr University of Medical Sciences, Medical Faculty
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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