

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Clinical Trials Comparison Time of Administration of Clomiphene Citrate on Follicular Growth, Endometrial Thickness, Ovulation and Pregnancy Rates in Polycystic Ovary Syndrome Patients

Protocol summary

Summary

This clinical trial study aimed to compare the onset of clomiphene citrate at the luteal phase and the third menstrual day, and its effect on the growth of ovarian follicles, endometrial thickness and rate of ovulation and pregnancy in 115 women with polycystic ovary syndrome referred to Fatemeh Zahra Infertility Center of Babol. All patients were received 10 mg of medroxyprogesterone acetate 14 days after period for 10 days, then patients were randomly divided into two groups based on random numbers table. The patients in intervention group (55 Patients) was received 100 mg clomiphene for 5 days at the luteal phase immediately after completion of medroxyprogesterone and in the control group (60 Patients) at the third menstrual, and on day 11 of the cycle, transvaginal ultrasound was done for all patients. If there was at least a follicle larger than 18 mm, 10 thousand units of Human chorionic gonadotropin was injected intramuscularly. The preliminary results including the follicular growth and endometrial thickness and number of dominant follicles and Secondary outcomes including pregnancy and abortion were compared in the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016052125292N4**
Registration date: **2016-09-01, 1395/06/11**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-09-01, 1395/06/11

Registrant information

Name

Sedigheh Smaeilzadeh

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3223 8301

Email address

crdu.rohan@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Babol University of Medical Science

Expected recruitment start date

2012-03-19, 1390/12/29

Expected recruitment end date

2013-03-19, 1391/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical Trials Comparison Time of Administration of Clomiphene Citrate on Follicular Growth, Endometrial Thickness, Ovulation and Pregnancy Rates in Polycystic Ovary Syndrome Patients

Public title

Effect Time of Administration of Clomiphene citrate on the Fertility of patients with Polycystic Ovary Syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with Polycystic Ovary Syndrome and undergoing Intrauterine insemination; Age 18 to 35 years; duration of infertility less than 5 years; normal hysterosalpingography and normal spermogram; No previous use of gonadotropin
Exclusion criteria: Follicle-stimulating hormone base of more than or equal to 14; Ovarian pathology; There is an ovary; Absence due to male factor infertility; endometriosis; tubal obstruction

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **115**

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

Ethics Committee of Babol University of Medical Science

Street address

Ganj Afrouz Street

City

Babol

Postal code

Approval date

2012-03-03, 1390/12/13

Ethics committee reference number

MUBABOL.REC.1390.13

Health conditions studied

1

Description of health condition studied

polycystic ovarian syndrome

ICD-10 code

E28.2

ICD-10 code description

polycystic ovarian syndrome

Primary outcomes

1

Description

On Follicular Growth, Endometrial Thickness and Ovulation

Timepoint

11 day menstrual cycle

Method of measurement

With transvaginal sonography in millimeters

Secondary outcomes

1

Description

Pregnancy

Timepoint

16 days after injection of Human Chorionic Gonadotropin

Method of measurement

B-Human Chorionic Gonadotropin test serum

Intervention groups

1

Description

Intervention group: The patients was received 100 mg clomiphene for 5 days at the luteal phase immediately after completion of medroxyprogesterone

Category

Treatment - Drugs

2

Description

Control group: The patients was received 100 mg clomiphene for 5 days at the third menstrual

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Center of fertility infertility Fateme Zahra of Babol

Full name of responsible person

Mohadeseh Mahdavi

Street address

Above the bridge Mohammah Hassan Khan, Tork Mahaleh

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Babol University of
Medical Science

Full name of responsible person

Mahmoud Babaie

Street address

Iran- Babol -Ganj Afrouz Street

City

Babol

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 of Babol University of
Medical Science

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

Babol University of Medical Science

Full name of responsible person

Mohadeseh Mahdavi

Position

MD

Other areas of specialty/work

Street address

Iran- Babol- Ganj Afrouz Street

City

Babol

Postal code

Phone

+98 11 3223 8301

Fax

Email

mojy_rad@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Babol University of Medical Science

Full name of responsible person

Mahtab Zeinalzadeh

Position

Obstetrician and Gynecologist

Other areas of specialty/work

Street address

Ganj Afrouz Street- Babol- Iran

City

Babol

Postal code

Phone

+98 911 114 1577

Fax

Email

zeinalmahtab@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Babol University of Medical Science

Full name of responsible person

Mohadeseh Mahdavi

Position

MD

Other areas of specialty/work

Street address

Ganj Afrouz Street- Babol-Iran

City

Babol

Postal code

Phone

+98 11 3223 8301

Fax

Email

mojy_rad@yahoo.com

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