

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Comparison of adding Tamoxifen or Gonadotropin to Clomiphene for induction ovulation in Polycystic Ovary Syndrome (PCOS) patients resistance to Clomiphene

Protocol summary

Summary

Clomiphene citrate (CC) is used as first line treatment in PCOS patients but Patient may resistant to CC up to 25% and its pregnancy rate is 40%. One of the causes of low pregnancy rate by CC related to its possible antiestrogenic effect on endometrium. Tamoxifen (Tom) is a similar drug which has less antiestrogenic effect on endometrium and cervical mucus. Also, ovulation induction with Gonadotropin is successful in these patients but it is expensive and extensive monitoring that is necessary because of the high sensitivity of polycystic ovaries to exogenous gonadotropin, with a high risk of ovarian hyperstimulation (OHSS), cycle termination, multiple pregnancy, and abortion. Aim: The aim of this study is the comparison of adding Tamoxifen or gonadotropin to CC in CC-resistant PCOS patients to improve ovulation. Inclusion criteria: PCOS CC resistance Patients with age between 18 and 35 years, ... Exclusion criteria: hyperprolactinaemia, hypercorticism or thyroidism, pelvic pathology or surgery, ... Materials and Methods: This double-blind randomized controlled trial study was performed on 200 infertile PCOS patients that referred to Fatemeh-Zahra Infertility and Reproductive Health Research Center from 2010 to 2011. In addition to the CC (100 mg/day) from day 3 to day 9 of the cycle day, each patient was selected randomly to receive either Tom; 20mg/day (group I), or Gonadotropin HMG; 75mg/day in cycle day 7, 8, 9. (group II). Outcome: Rate of ovulation, pregnancy, dominant follicle, and endometrial thickness are compared in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138904121760N8**
Registration date: **2010-11-04, 1389/08/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-11-04, 1389/08/13

Registrant information

Name

Nargess Gholizadeh Pasha

Name of organization / entity

Fatemehzahra Infertility Reproductive Health Research Center, Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

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zahra@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology, Babol University of Medical Sciences

Expected recruitment start date

2010-09-23, 1389/07/01

Expected recruitment end date

2011-08-23, 1390/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of adding Tamoxifen or Gonadotropin to Clomiphene for induction ovulation in Polycystic Ovary Syndrome (PCOS) patients resistance to Clomiphene

Public title

Comparison of adding Tamoxifen or Gonadotropin to Clomiphene for induction ovulation in Polycystic Ovary Syndrome (PCOS) patients resistance to Clomiphene

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: PCOS Clomiphene citrate resistance
Patients with age between 18 and 35 years, years period of infertility between 1.5-5 yr and BMI between 19-35.

Exclusion criteria: hyperprolactinaemia, hypercorticism or thyroidism, pelvic pathology or surgery, infertility factor other than anovulation excluded.

Age

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

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The ethics committee of Babol University of Medical sciences

Street address

Gangafoz Avenue, Babol University of Medical sciences

City

Babol

Postal code

Approval date

2010-09-13, 1389/06/22

Ethics committee reference number

1021

Health conditions studied

1

Description of health condition studied

Polycystic Ovary Syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic Ovary Syndrome

Primary outcomes

1

Description

Dominant follicle

Timepoint

12 -16 menstrual cycle

Method of measurement

sonography

2

Description

Rate ovulation

Timepoint

36-38 days after HCG injection

Method of measurement

sonography

3

Description

Endometrial thickness

Timepoint

at HCG injection day

Method of measurement

sonography

Secondary outcomes

1

Description

Occurrence of pregnancy

Timepoint

25 days after HCG injection

Method of measurement

sonography

Intervention groups

1

Description

Intervention Group: Clomiphene Citrate (150mg) plus Tamoxifen (20mg), third day of menstrual cycle for 5 days

Category

Treatment - Drugs

2

Description

Control group: Standard method including 150 mg of Clomiphene daily, with Gonadotropin in sixth, seventh and eighth days of menstrual cycle

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemah Zahra Fertility & Reproductive health training center

Full name of responsible person

Maedeh Ghafari

Street address

Fatemehzahra Fertility & reproductive health training center, Noshirvani street

City

Babol

2

Recruitment center

Name of recruitment center

Mehregan Medical Center

Full name of responsible person

Dr. Zahra Basirat

Street address

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology, Babol University of Medical Sciences

Full name of responsible person

Dr. Ali Bijani

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Babol University of Medical Sciences, Gangafroz Avenue

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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 for Research and Technology, 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

Fatemehzahra Fertility & reproductive Health Reseach Center

Full name of responsible person

Nargess Gholizadeh Pasha

Position

MA/Responsible for Public Affairs of Research Center

Other areas of specialty/work

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Other areas of specialty/work**Street address**

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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