Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

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

Protocol summary

Summary

Clomiphen 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 endometer. Tomoxiphen(Tom) is a similar drug which has less antiestegenic effect on endometer and cervical mucous. 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 Tomoxiphen or gonaditropin to CC in cc-resistant PCOS patients to improve ovulation. Inclusion citeria: 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

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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 Clomiphen 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
Gangafroz 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 Ghafori
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
Babol

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
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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