Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jul 2026

Use of dexamethasone and clomiphene citrate in patients with polycystic ovarian syndrome resistant to clomiphene citrate

Protocol summary

Summary

The aim of this study was to evaluate the efficacy of adding dexamethasone (dex) to clomiphene citrate (CC) in CC-resistant polycystic ovarian syndrome (PCOS) patients to improve ovulation. This study was performed on infertile PCOS patients that referred to Fateme-Zahra Infertility and Reproductive Health Research Center of Babol from 2007 to 2009. Sixty Patients divided in two groups and stimulation was done with dex+CC or placebo+CC. Main outcome measurements were rate of ovulation, pregnancy and matured follicles.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138807041760N2**
Registration date: **2010-05-21, 1389/02/31**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-05-21, 1389/02/31

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)

Phone

+98 11 3236 2282

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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

2008-08-22, 1387/06/01

Expected recruitment end date

2009-03-21, 1388/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Use of dexamethasone and clomiphene citrate in patients with polycystic ovarian syndrome resistant to clomiphene citrate

Public title

Use of dexamethasone and clomiphene citrate in patients with polycystic ovarian syndrome resistant to clomiphene citrate

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: having PCOS according to the Rotterdam criteria for diagnosis of PCOS, age between 18 and 35 years, period of infertility >1/5 years and normal DHEAS levels. Exclusion criteria: hyperprolactinaemia, hypercorticism or thyroidism, pelvic pathology or surgery, infertility factor other than anovulation.

Age

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

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

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

City

Babol

Postal code

4717641367

Approval date

2010-02-27, 1388/12/08

Ethics committee reference number

1008

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

ovulation

Timepoint

36-48 hr after HCG injection

Method of measurement

fluid in the cul-de-sac or corpus luteum formation, disappearance of pre-ovulatory follicle

2

Description

pregnancy

Timepoint

25 days after HCG administration

Method of measurement

transvaginal ultrasound examination

Secondary outcomes

1

Description

number of matured follicles

Timepoint

12-18 days after first of menstuaration

Method of measurement

sonography

Intervention groups

1

Description

Group I: Clomiphene Citrate, 100 mg, was given from 3rd day until 7th day plus dexamethasone 2mg/day orally in two divided doses

Category

Treatment - Drugs

2

Description

Group 2: Clomiphene Citrate, 100 mg, was given from 3rd day until 7th day plus folic acid tab from 3rd day until 12th day

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemehzahra Fertility & infertility hospital

Full name of responsible person

Seddigheh Esmaeilzadeh

Street address

Noshirvani steert

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
Ali Bijani
Street address
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 Research Center
Full name of responsible person
Nargess Gholizadeh Pasha
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Person responsible for updating data

Contact

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