

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 2026

Pioglitazone hydrochloride in combination with clomiphen citrate (CC) in ovulation and pregnancy induction among patients with polycystic ovary syndrome: A randomized, placebo controlled study

Protocol summary

Summary

This is a double blind clinical trial with the aim of comparison of combination therapy of clomiphen citrate with pioglitazone or placebo in induction of ovulation and pregnancy among patients with polycystic ovary syndrome. This study will be conducted in Hormozgan University of Medical Sciences in 2013. Study population are all of the patients with confirmed polycystic ovary syndrome. Estimated sample size is 49 patients. Inclusion criteria consisting patients aged between 18 and 35 years and with history of anovulatory cycles during past two months in addition to one of the following conditions: Serum progesterone level less than 5 mg during the mid-luteal phase; Hirsutism; Positive response to medroxy-progesterone acetate withdrawal test ; Serum testosterone level higher than 65 Ng/Dl Exclusion criteria comprising patients with confirmed diabetes mellitus or fasting blood glucose higher than 125 mg/dl; congenital adrenal hyperplasia which was confirmed by 17-alpha hydroxy progesterone level of 200 ng/dl or higher; patients with underlying disorders such as thyroid disease; hyperprolactinemia; congenital heart disease; hypertension; renal and liver dysfunction; patients who had received any hypoglycemic agent or inducing ovulation medications during 30days ago. All of the participants provided informed consent. The participants will be followed up for 3 months, ovulation and pregnancy rate among the both groups will be documented. The complications of these methods also, will be recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013071013932N1**
Registration date: **2013-09-14, 1392/06/23**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-09-14, 1392/06/23

Registrant information

Name

Seyed Shojaeddin Namazi

Name of organization / entity

Hormozgan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 74 1333 4190

Email address

ssh.namazi@gmail.com

Recruitment status

Recruitment complete

Funding source

Hormozgan University of Medical Sciences

Expected recruitment start date

2013-03-20, 1391/12/30

Expected recruitment end date

2013-09-23, 1392/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Pioglitazone hydrochloride in combination with clomiphen citrate (CC) in ovulation and pregnancy induction among patients with polycystic ovary

syndrome: A randomized, placebo controlled study

Public title

The efficacy of combination therapy of clomiphen citrate and pioglitazone in induction ovulation and pregnancy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with history of anovulatory cycles during the past two months in addition to one of the following conditions: Serum progesterone level less than 5 mg during the mid-luteal phase; Hirsutism; Positive response to medroxy-progesterone acetate withdrawal test; Serum testosterone level higher than 65 Ng/Dl Exclusion criteria; patients with confirmed diabetes mellitus or fasting blood glucose higher than 125 mg/dl; congenital adrenal hyperplasia which was confirmed by 17-alpha hydroxy progesterone level of 200 ng/dl or higher; patients with underlying disorders such as thyroid disease; hyperprolactinemia; congenital heart disease; hypertension; renal and liver dysfunction; patients who had received any hypoglycemic agent or inducing ovulation medications during 30days ago.

Age

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

Gender

Female

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **49**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Hormozgan University of Medical Science

Street address

Research Council building, Shahid Mohammadi Hospital, Jomhoori Eslami Blvd

City

Bandar Abbas

Postal code

Approval date

2013-08-20, 1392/05/29

Ethics committee reference number

HEc-92-4-25-3

Health conditions studied

1

Description of health condition studied

Poly cystic Ovary Syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic Ovarian Syndrome

Primary outcomes

1

Description

ovulation

Timepoint

one month after intervention

Method of measurement

vaginal bleeding

Secondary outcomes

1

Description

pregnancy

Timepoint

2 month after intervention

Method of measurement

beta human chorionic gonadotropine of serum

Intervention groups

1

Description

All of the patients will be received 4 mg of pioglitazone twice a day for 5 days.

Category

Treatment - Drugs

2

Description

All of the patients will be received 4 mg of pioglitazone twice a day for 5 days after that subjects will be received 50 mg of clomiphen citrate twice a day for 5 days in addition to pioglitazone while, control group will be received a placebo instead of clomiphen in the second 5 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

Seyed Shojaeddin Namazi

Street address

City

Bandar Abbas

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hormozgan University of Medical Science

Full name of responsible person

Seyed Shojaeddin Namazi

Street address

Student Research Committee, Research Council,
Shahid Mohammadi Hospital, Jomhoori Eslami Blvd

City

Bandar Abbas

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Hormozgan 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hormozgan University of Medical Science

Full name of responsible person

Seyed Shojaeddin Namazi

Position

Student

Other areas of specialty/work

Street address

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Web page address

Person responsible for updating data

Contact

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Hormozgan University of Medical Sciences

Full name of responsible person

Seyed Shojaeddin Namazi

Position

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Other areas of specialty/work

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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