

# 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**

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

**City**

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**Phone**

+98 76 1335 0218

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**Email**

ssh.namazi@gmail.com

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Hormozgan University of Medical Sciences

**Full name of responsible person**

Seyed Shojaeddin Namazi

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Student

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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*