

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### Efficiency of low dose aspirin for prevention of ovarian hyper stimulation syndrome for in vitro fertilization cycles of the patient with polycystic ovarian syndrome

#### Protocol summary

##### Summary

Goal: To evaluate the efficiency of low dose aspirin for prevention of ovarian hyper stimulation syndrome for in vitro fertilization cycles of the patient with polycystic ovarian syndrome (PCOS). Study population: Based on modified Rotterdam criteria, 80 PCOS patients will be selected. Inclusion criteria: Polycystic ovarian syndrome (PCOS) will be confirmed by the presence of 1- Hyperandrogenism (clinical and/or biochemical), and 2- Ovarian dysfunction (oligo-anovulation and/or polycystic ovaries), and 3-The exclusion of other androgen excess or related disorders. Exclusion criteria: All of the patients with Known hypersensitivity to ASA or previous gastritis or GI bleeding will be excluded. Patients with PCOS who need IVF will be divided to 2 groups: 1- For the first group 100mg ASA will be started since the 21th day of the previous cycle. 2- for the second group placebo will be started since the 21th cycle day. Other steps of IVF protocol will be the same for both groups: Gonadotropin Releasing Hormone (GnRH) agonist starts from the 21th day of previous cycle to the Human Chorionic Gonadotropin (HCG)-day. Human Menopausal Gonadotropin (HMG) and Gonal-f one ampul /day starts from the 2nd cycle day and follicl monitoring by ultrasound starts from the 6th cycle day. HCG is injected when the follicles reach the appropriate size and ovum pick up will be done. The total follicular count, serum estradiol level and ovarian size will be evaluated for the evidence of OHSS.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201105216541N1**

Registration date: **2011-06-18, 1390/03/28**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2011-06-18, 1390/03/28

##### Registrant information

###### Name

Bahia Namavar Jahromi

###### Name of organization / entity

Shiraz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 1233 2365

###### Email address

namavarb@sums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Infertility research center, Shiraz University of Medical Sciences

##### Expected recruitment start date

2011-05-01, 1390/02/11

##### Expected recruitment end date

2013-06-28, 1392/04/07

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Efficiency of low dose aspirin for prevention of ovarian hyper stimulation syndrome for in vitro fertilization cycles of the patient with polycystic ovarian syndrome

##### Public title

Efficiency of low dose aspirin for prevention of complications for in vitro fertilization cycles of the patient with polycystic ovarian syndrome

#### **Purpose**

Treatment

#### **Inclusion/Exclusion criteria**

Inclusion criteria: polycystic ovarian syndrome (PCOS) confirmed by: Hyperandrogenism (clinical and/or biochemical); Ovarian dysfunction (oligo-anovulation and/or polycystic ovaries); The exclusion of other androgen excess or related disorders. Exclusion criteria: All of the patients with Known hypersensitivity to ASA or previous gastritis or GI bleeding.

#### **Age**

From **18 years** old to **40 years** old

#### **Gender**

Female

#### **Phase**

2

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **80**

#### **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**

Ethics comitee of Shiraz University of Medical Sciences

###### **Street address**

Shiraz University of Medical Sciences

###### **City**

Shiraz

###### **Postal code**

##### **Approval date**

2010-08-20, 1389/05/29

##### **Ethics committee reference number**

ct-89-5522

### **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**

number of follicles

##### **Timepoint**

every 3-4 days

##### **Method of measurement**

by Ultra sound scan

#### **2**

##### **Description**

serum Estradiol

##### **Timepoint**

every 3-4 days

##### **Method of measurement**

serum level of Estradiol

### **Secondary outcomes**

#### **1**

##### **Description**

ovarian size more than 5 cm

##### **Timepoint**

3-4 days

##### **Method of measurement**

ultra sound

#### **2**

##### **Description**

ovarian size more than12 cm

##### **Timepoint**

3-4 days

##### **Method of measurement**

ultra sound

### **Intervention groups**

#### **1**

##### **Description**

For the intervention group 100mg/day aspirin will be started since the 21th day of the previous cycle.

##### **Category**

Treatment - Drugs

#### **2**

##### **Description**

A placebo with a similar shape will be started for the control group since the 21th day of previous cycle.

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Infertility center of Ghadir Hospital

**Full name of responsible person****Street address****City**

Shiraz

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Infertility research center, Shiraz university of Medical Sciences

**Full name of responsible person**

Dr. Jale Zolghadr

**Street address**

Dep. of OB-GYN, Shahid Faghihi Hospital, Zand street

**City**

Shiraz

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Infertility research center, Shiraz 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**

Infertility research center, Shiraz university of Medical Sciences

**Full name of responsible person**

Dr. Bahia Namavar Jahromi

**Position**

Associate professor

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

Dep. of OB-GYN, Shahid Faghihi Hospital, Zand street

**City**

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**Postal code****Phone**

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Infertility research center, Shiraz University of Medical Sciences

**Full name of responsible person**

Dr. Jale Zolghadr

**Position**

Associate professor

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

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**City**

Shiraz

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jzolghad@yahoo.com

**Web page address****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*