

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 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 follicle 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

Shiraz

Postal code

Phone

+98 71 1233 2365

Fax

Email

namavarb@sums.ac.ir

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

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

City

Shiraz

Postal code

Phone

+98 71 1233 2365

Fax

Email

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