

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Effect of low-dose aspirin before IVF to prevent ovarian hyperstimulation syndrome (OHSS)

Protocol summary

Study aim

Determination of ASA effect on incidence and severity of OHSS in patients undergoing IVF

Design

A phase 2 interventional study consisted of intervention group (20 patients) recruited based on inclusion criteria. Data of control group (20 patients) will be extracted from patients with same characteristics underwent IVF regimen (without ASA)

Settings and conduct

The study will be conducted in Kerman Afzalipoor Hospital. The intervention group will be administered low dose ASA two weeks before the start of menstrual cycle and will receive Cinnal-F on day 3 of the cycle and after 6 days, on 9th day of the cycle, vaginal sonography will be performed. As the follicle size reached 12 to 14 mm, antagonist will be administered and as the size of follicles reached 16-18 mm, 1 cc Buserelin and 5000 units of hcg will be administered and 36 hours later, ovarian puncture will be done. Patients will be given charts to follow their OHSS related symptoms. Three days after the puncture, laboratory and sonographic data will be obtained and evaluated.

Participants/Inclusion and exclusion criteria

Inclusion criteria : Female patients planned to treat with antagonist protocol ART (Assisted Reproductive Technology) Having PCO criteria (Including AMH level more than 4 ng/ml, Sonogram suggestive of PCO, and Oligomenorrhea) Exclusion : Lack of consent to participate

Intervention groups

Patients will be administered low dose ASA 80 mg 2 weeks before their menstrual cycle

Main outcome variables

OHSS incidence and Severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210730052019N2**

Registration date: **2021-08-28, 1400/06/06**

Registration timing: **registered_while_recruiting**

Last update: **2021-08-28, 1400/06/06**

Update count: **0**

Registration date

2021-08-28, 1400/06/06

Registrant information

Name

Mehran Ilaghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3251 7779

Email address

mehran-ilaghi@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-25, 1400/06/03

Expected recruitment end date

2021-09-11, 1400/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of low-dose aspirin before IVF to prevent ovarian hyperstimulation syndrome (OHSS)

Public title

Effect of low-dose aspirin on OHSS

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Female patients planned to treat with antagonist protocol ART (Assisted Reproductive Technology) Having PCO criteria (Including AMH level more than 4 ng/ml, Sonogram suggestive of PCO, and Oligomenorrhea)

Exclusion criteria:

Lack of consent to participate

Age

No age limit

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 20

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features

The intervention group will be recruited in this study. For the control group, existing data will be used. The control group in this study consists of patients with PCO criteria who had previously undergone IVF with the same regimen as Intervention group (Except for ASA). Data of this group is extracted from patients files in infertility ward of Kerman Afzalipor Hospital and will be used as the control to compare the outcomes of OHSS in intervention group. These patients, regarding the aforementioned criteria, will be selected using random sampling. Therefore, in this study, patient recruitment will occur for intervention group.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kerman University of Medical Sciences

Street address

Haftbagh-Alavi highway, Kerman University of medical Sciences

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2020-05-12, 1399/02/23

Ethics committee reference number

IR.KMU.AH.REC.1399.018

Health conditions studied**1****Description of health condition studied**

Infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes**1****Description**

OHSS Incidence

Timepoint

Throughout the study based on patients symptoms or on the third day after puncture based on laboratory and sonographic findings

Method of measurement

Patient symptoms monitoring sheets - Laboratory findings (Rise of liver enzymes, creatinine, hematocrit), sonographic findings (ascites)

2**Description**

OHSS Severity

Timepoint

Throughout the study based on patients symptoms or on the third day after puncture based on laboratory and sonographic findings

Method of measurement

Patient symptoms monitoring sheets - Laboratory findings (Rise of liver enzymes, creatinine, hematocrit), sonographic findings (ascites)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: The study will be conducted in Kerman Afzalipoor Hospital. The intervention group will be administered low dose ASA two weeks before the start of menstrual cycle and will receive Cinnal-F on day

3 of the cycle and after 6 days, on 9th day of the cycle, vaginal sonography will be performed. As the follicle size reached 12 to 14 mm, antagonist will be administered and as the size of follicles reached 16-18 mm, 1 cc Buserelin and 5000 units of hcg will be administered and 36 hours later, ovarian puncture will be done. Patients will be given charts to follow their OHSS related symptoms. Three days after the puncture, laboratory and sonographic data will be obtained and evaluated.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour hospital

Full name of responsible person

Victoria Habibzadeh

Street address

Imam Khomeini highway, Afzalipoor hospital

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afzalipoorhospital@kmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Davood Kalantar

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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

Kerman University of Medical Sciences

Proportion provided by this source

1

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Victoria Habibzadeh

Position

Professor, Obstetrics and gynecology specialist

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Victoria Habibzadeh

Position

Professor, Obstetrics and gynecology specialist

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Person responsible for updating data

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable