

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Comparison the effect of 3 days with 7 days GnRH-antagonist in prevention of ovarian hyperstimulation syndrome(OHSS) in women undergoing assisted reproductive technology (ART)

Protocol summary

Study aim

Comparison of the effect of 3-day and 7-day GnRH antagonist therapy in prevention of ovarian hyperstimulation syndrome (OHSS) in women undergoing assisted reproductive technology (ART)

Design

Clinical trial with phase 4 parallel groups on 40 patients

Settings and conduct

Tehran Shariati Hospital and Birjand Infertility Center

Participants/Inclusion and exclusion criteria

1. Having informed consent to enter the study 2. The possibility of useful intervention on individuals 3. Age between 18 to 40 years 4. The person is at risk for OHSS syndrome (for example, the number of recovered eggs is more than 15 or serum estradiol more than 3000 pg / ml) 5. Any person who does not meet any of the exclusion criteria will be included in the study if satisfied. 1. Dissatisfaction to enter the study 2. Age less than 18 years or more than 40 years 3. Any disease that interferes with the intended intervention. 4. Patient with diabetes / hemophilia or coagulation disorder 5. Patients with pulmonary fibrosis, swelling or inflammation around the heart or lungs, high blood pressure, liver disease, heart valve disease or allergy to cabergoline or ergot derivatives 6. Taking drugs that affect the incidence of OHSS syndrome (calcium gluconate / metformin / letrozole / other GnRH-ant antagonists) 7. Pregnancy during the study cycle 8. Contraindicated cases that are considered by the expert and are not included in the test.

Intervention groups

Women 18 to 40 years old under ART who are at risk for OHSS. Half of the patients will receive 3-day treatment after egg retrieval and the other half will receive 7-day treatment with steroids to prevent OHSS syndrome.

Main outcome variables

OHSS rate in each group

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201126049497N1**

Registration date: **2021-11-09, 1400/08/18**

Registration timing: **registered_while_recruiting**

Last update: **2021-11-09, 1400/08/18**

Update count: **0**

Registration date

2021-11-09, 1400/08/18

Registrant information

Name

Vajihe Hazari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3243 6691

Email address

vajihehazari@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-18, 1400/07/26

Expected recruitment end date

2022-08-23, 1401/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of 3 days with 7 days GNRH-antagonist in prevention of ovarian hyperstimulation syndrome(OHSS) in women undergoing assisted reproductive technology (ART)

Public title

Comparison the effect of 3 day with 7 day GNRH-antagonist in prevention of ovarian hyperstimulation syndrome(OHSS)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having informed consent to enter the study. The possibility of useful intervention on individuals. Age between 18 and 40 years. The person is at risk for OHSS syndrome (for example, the number of recovered eggs is more than 15 or serum estradiol more than 3000 pg / ml Any person who does not meet any of the exclusion criteria will be included in the study if satisfied

Exclusion criteria:

Dissatisfaction to enter the study Age less than 18 years or more than 40 years Any disease that interferes with the intended intervention. Patient with diabetes / hemophilia or coagulation disorder Patients with pulmonary fibrosis, swelling or inflammation around the heart or lungs, high blood pressure, liver disease, heart valve disease, or allergy to cabergoline or ergot derivatives Use of drugs that affect the development of OHSS syndrome (calcium gluconate / metformin / letrozole / other GNRH-ant antagonists) Pregnancy during the study cycle Contraindications that are considered by a specialist and are not included in the test.

Age

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

Gender

Female

Phase

2

Groups that have been masked

- Investigator

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, due to the different time of consumption, it is not possible to blind the subject, but the researcher who examines the outcome will be blind. Of course, it should be noted that the study outcome is such that non-blindness does not affect the outcome (it is an objective outcome)

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Birjand University of Medical Sciences

Street address

Ghaffari Street, Birjand

City

Birjand

Province

South Khorasan

Postal code

9717853577

Approval date

2021-10-09, 1400/07/17

Ethics committee reference number

IR.BUMS.REC.1400.191

Health conditions studied

1

Description of health condition studied

Ovarian hyperstimulation syndrome

ICD-10 code

N98.1

ICD-10 code description

Hyperstimulation of ovaries

Primary outcomes

1

Description

Ovarian hyperstimulation syndrome

Timepoint

One week after OPU

Method of measurement

Clinical and laboratory evaluation and sonography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: drug(cetrotide) for 3 days

Category

Treatment - Drugs

2

Description

Intervention group:drug(cetrotide) for 7 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility ward of Shariati Hospital in Tehran

Full name of responsible person

vajihe hazari

Street address

No 16, soraya avey, Tohid St, Birjand

City

birjand

Province

South Khorasan

Postal code

9718877655

Phone

+98 56 3243 6691

Email

vajihehazari@bums.ac.ir

2

Recruitment center

Name of recruitment center

Rooyesh Infertility Center of Birjand

Full name of responsible person

Vajihe hazari

Street address

No 16, soraya avey, Tohid St, Birjand

City

Birjand

Province

South Khorasan

Postal code

9718877655

Phone

+98 56 3243 6691

Email

vajihehazari@bums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

vajihe hazari

Street address

No 16, soraya avey, Tohid St, Birjand

City

Birjand

Province

South Khorasan

Postal code

9718877655

Phone

+98 56 3243 6691

Email

vajihehazari@bums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Birjand University of Medical Sciences

Proportion provided by this source

100

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

Birjand University of Medical Sciences

Full name of responsible person

vajihe hazari

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

No 16, soraya avey, Tohid St, Birjand

City

Birjand

Province

South Khorasan

Postal code

9718876655

Phone

+98 56 3243 6691

Email

vajihehazari@bums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

vajihe hazari

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

No 16, soraya avey, Tohid St, Birjand

City

birjand

Province

South Khorasan

Postal code

9718877655

Phone

+98 56 3243 6691

Email

vajihehazari@bums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

vajihe hazari

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

No 16, soraya avey, Tohid St, Birjand

City

Birjand

Province

South Khorasan

Postal code

9718876655

Phone

+98 56 3243 6691

Email

vajihehazari@bums.ac.ir

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

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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