Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 disorde 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