Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 2026

Comparison of ovulation induction by GnRH antagonist (Cetrotide) in patients with poor ovarian response with the previous ART(Assisted Reproductive Technology) cycles

Protocol summary

Summary

The main objective of this study is determining the outcome of antagonist ovulation GnRH (Cetrotide) in infertile women with poor ovarian response in the previous ART (Assisted Reproductive Technology). Inclusion criteria: history of poor response to stimulation (<3 dominant follicles or estradiol <500pg/ml), basal FSH level>10 mIU/ml, antral follicle count <5. Exclusion criteria: endometriosis, only one ovary, endocrine or metabolic disorder. Forty poor responders in previous ART which performed three months earlier are selected and the data of their previous cycle such as the number of follicle and oocyte, the number and the quality of embryo …, retrieve from documents. Medical orders are given as follow: Fustimone 300 unites daily after third day and vaginal sonography after ninth day of cycle are initiated. If in first sonography, follicles with 14mm diameter or more cannot identified, sonography is performed every two days until 14mm follicle can be seen and then Cetrotide (0.1mg/day) will be injected and Fustimone and daily sonography will be sustained. When one or two 16 to 18mm follicles are detected in sonography, 1000 unit of HCG is injected and the two previous drugs will be discontinued. Thirty six hours after HCG injection, puncture of ovary is performed and oocytes are sent to laboratory and the quality and quantity of them will be documented. The grading of embryo is determined numerically and recorded. The data related to follicles' number in sonography and retrieved oocytes will be compared with the records of previous cycle.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014100819464N1**

Registration date: **2014-11-19, 1393/08/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-11-19, 1393/08/28

Registrant information

Name

Victoria Habibzadeh

Name of organization / entity

Kerman University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kerman University of Medical Sciences

Expected recruitment start date

2013-05-22, 1392/03/01

Expected recruitment end date

2014-05-22, 1393/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of ovulation induction by GnRH antagonist

(Cetrotide) in patients with poor ovarian response with the previous ART(Assisted Reproductive Technology) cycles

Public title
Comparison of ovulation induction by GnRH antagonist (Cetrotide) in patients with poor ovarian response with the previous ART(Assisted Reproductive Technology) cycles
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: history of poor response to stimulation (<3 dominant follicles or estradiol <500pg/ml), basal FSH level>10 mIU/ml, antral follicle count <5. Exclusion criteria: endometriosis,only one ovary, endocrine or metabolic disorder.
Age
No age limit
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
The ethics committee of Kerman University of Medical sciences
Street address
Shafa Square
City
Kerman
Postal code
Approval date
2013-09-21, 1392/06/30
Ethics committee reference number
k/92/288

Health conditions studied

1

Description of health condition studied
Poor ovarian Responders
ICD-10 code
E28.8
ICD-10 code description
Other ovarian dysfunction

Primary outcomes

1

Description
Pregnancy
Timepoint
7-6 weeks after intervention
Method of measurement
Ultrasound

Secondary outcomes

1

Description
Endometrial thickness
Timepoint
Day of HCG injection
Method of measurement
Ultrasound

2

Description
Estradiol levels
Timepoint
Day of HCG injection
Method of measurement
Ultrasound

3

Description
The number of oocytes recovered
Timepoint
Day puncture
Method of measurement
Laboratory

4

Description
No. of fertilized oocytes
Timepoint
Day of embryo transfer
Method of measurement
Laboratory

5

Description
The amount of transferred embryos
Timepoint
Day of embryo transfer
Method of measurement
Laboratory

Intervention groups

1

Description
Intervention: Antagonist regimen (Fustimone 300 unites daily after third day and vaginal sonography after ninth day of cycle are initiated. When 14mm follicle can be seen Cetrotide (0.1mg/day) will be injected. When one or two 16 to 18mm follicles are detected in sonography, 1000 unit of HCG is injected and the two previous drugs will be discontinued.)
Category
Treatment - Drugs

2

Description
Control: according to previous AVF method performed and documented in medical records of patient
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Afzalipoor Hospital
Full name of responsible person
Sonia Ahmadi
Street address
Afzalipoor Hospital, Zendan Square
City
Kerman

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Kerman University of Medical Sciences
Full name of responsible person
Fatemeh Hassani
Street address
Tahmasbabad Square, Ebnesina Street
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Kerman
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Kerman 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
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Person responsible for scientific inquiries

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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