

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

Iran (Islamic Republic of)

Phone

+98 342322250

Email address

v_habibzadeh@kmu.ac.ir

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

City

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

Kerman University of Medical Sciences

Full name of responsible person

Sonia Ahmadi

Position

Assistant of gynecology

Other areas of specialty/work

Street address

Afzalipoor Hospital, Zendan Square

City

Kerman

Postal code

Phone

+98 34 1223 5011

Fax

Email

soni.ahmadi@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Victoria Hbibzadeh

Position

gynecologist

Other areas of specialty/work

Street address

Afzalipoor Hospital, Zendan Square

City

Kerman

Postal code

Phone

+98 34 3223 5011

Fax

Email

v_habibzadeh@kmu.ac.ir

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