

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Adjuvant growth hormone therapy in antagonist protocol in poor responders undergoing assisted reproductive technology

Protocol summary

Summary

Management of poor responders to ovarian stimulation consists about 9-18% of the patients undergoing IVF and it is one of the most important problems in assisted reproductive techniques (ART). The aim of the present study is to evaluate the effect of addition of growth hormone to antagonist regimen in poor responders in assisted reproductive cycles. One hundred and twenty candidates of assisted reproductive technology referred to Yazd Research and Clinical Center for Infertility who have a history of one or more failed IVF or ICSI cycles with three or fewer retrieved oocytes, are prospectively randomized in two groups. In group I (60 patients), the antagonist regimen and in group II (60 patients), growth hormone 4 IU per day S.Q are added to antagonist protocol until the day of HCG injection. Main outcomes measures are: the number of follicles and oocytes, endometrial thickness, clinical and chemical pregnancy and implantation rates.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107296420N6**

Registration date: **2011-08-21, 1390/05/30**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-08-21, 1390/05/30

Registrant information

Name

Maryam Eftekhari

Name of organization / entity

Yazd Research and Clinical Center for Infertility

Country

Iran (Islamic Republic of)

Phone

+98 35182470856

Email address

eftekhari@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Yazd Research and Clinical Center for Infertility, Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2009-01-01, 1387/10/12

Expected recruitment end date

2011-01-01, 1389/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Adjuvant growth hormone therapy in antagonist protocol in poor responders undergoing assisted reproductive technology

Public title

Effect of growth hormone in IVF protocol

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: history of one or more failed in IVF cycles which three or fewer oocytes were been retrieved; serum estradiol's level in day of HCG injection <500 pg/ml; FSH in day 3 of cycle >10 and age>40 years. Exclusion criteria: Body mass index higher than 30; endocrine or metabolic disorder; endometriosis and severe male factor (azospermia).

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

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

Yazd reserch and clinical center for infertility

Street address

Bouali Ave, Safayeh

City

Yazd

Postal code

Approval date

2011-06-20, 1390/03/30

Ethics committee reference number

932

Health conditions studied

1

Description of health condition studied

infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

chemical pregnancy

Timepoint

2 weeks

Method of measurement

serum BHCG

Secondary outcomes

1

Description

number of oocyte

Timepoint

15 days

Method of measurement

numberring

2

Description

number of gonadotropin ampuls

Timepoint

15 days

Method of measurement

numberring

Intervention groups

1

Description

In study group: Patients in group I (growth hormone group) receive daily injection of 4 mg growth hormone from day 21 of previous cycle until the day of hCG injection. Ovarian stimulation is started from second day of menstrual cycle with 300 IU of HMG monitoring by serial vaginal sonography and measurement of serum E2 levels. When dominant follicles reach to 14 mm in mean diameter, 0.25mg/day of GnRH antagonist(cetrotide) is started and continued until the day of hCG injection, when at least two follicles with a mean diameter of 17 mm were observed 10000 IU hCG is injected and oocyte retrieval is done 35 hours later.

Category

Treatment - Drugs

2

Description

In control group: Patients in group II (control group); Ovarian stimulation is started from second day of menstrual cycle with 300 IU of HMG monitoring by serial vaginal sonography and measurement of serum E2 levels is done. When dominant follicles reach to 14 mm in mean diameter, 0.25mg/day of GnRH antagonist (cetrotide , sereno) is started and continued until the day of hCG injection, when at least two follicles with a mean diameter of 17 mm were observed 10000 IU hCG was injected . and oocyte retrieval is done 35 hours later.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd research and clinical center for infertility

Full name of responsible person

Maryam Eftekhari

Street address

Boali Ave., Safayeh

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd research and clinical center for infertility

Full name of responsible person

Dr Abbas Aflatoonian

Street address

Bouali Ave, Safayeh

City

Yazd

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yazd research and clinical center for infertility

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

Yazd research and clinical center for infertility

Full name of responsible person

Maryam Eftekhari

Position

Assisted professor of Obstetrics and Gynecology

Other areas of specialty/work

Street address

Yazd Research and Clinical Center for Infertility,
Bouali Ave, Safayeh

City

Yazd

Postal code

Phone

+98 35 1824 7085

Fax

Email

eftekhari@ssu.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd research and clinical center for infertility

Full name of responsible person

Maryam Eftekhari

Position

Assisted professor of Obstetrics and Gynecology

Other areas of specialty/work

Street address

Bouali Ave, Safayeh

City

Yazd

Postal code

8916877391

Phone

+98 35 1824 7085

Fax

Email

eftekhari@ssu.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Yazd research and clinical center for infertility

Full name of responsible person

Maryam Eftekhari

Position

Assisted professor of Obstetrics and Gynecology

Other areas of specialty/work

Street address

Bouali Ave, Safayeh

City

Yazd

Postal code

8916877391

Phone

+98 35 1824 7085

Fax

+98 35 1824 7087

Email

eftekhari@ssu.ac.ir

Web page address

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