

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Comparing effect of agonist & antagonist drugs of GnRh in ovulation stimulation in infertile couples with male factor (abnormalities of sperm production and sperm function and obstructions in the ductal system)

Protocol summary

Summary

To compare the effect of agonist & antagonist drugs of GnRh in ovulation stimulation in infertile couples with male factor (abnormalities of sperm production and sperm function obstructions in the ductal system). We recruited 42 persons as control group and 42 persons as intervention group. Inclusion criteria: 18-40 years old ladies, having no risk factor for infertility with infertile spouse. Intervention: injecting Gonal-F ampoule, from the 3rd day of cycle and then injecting Cetrotide ampoule, 0.25 mg daily till formation of at least two follicles 17-18 cm and several follicles 14-16 cm through testing by serial ultrasonography; then taking follicle through injecting HCG (human chorionic gonadotropin), after 36 hours. Primary outcome: number of dominant follicle; number of punctured ovule; number of eggs on the third day; number of clinical pregnancy; incidence of OHSS; therapy duration and cost.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111058010N1**
Registration date: **2012-02-13, 1390/11/24**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-02-13, 1390/11/24

Registrant information

Name

Maryam Hedayat

Name of organization / entity

Hamedan University of Medical Sciences & Health

Services

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Research Deputy, Hamedan University of Medical Sciences

Expected recruitment start date

2010-07-06, 1389/04/15

Expected recruitment end date

2012-02-18, 1390/11/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing effect of agonist & antagonist drugs of GnRh in ovulation stimulation in infertile couples with male factor (abnormalities of sperm production and sperm function and obstructions in the ductal system)

Public title

Comparing effect of agonist & antagonist drugs of Gonadotropin Releasing Hormone (GnRh) in ovulation stimulation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 18-40 years old ladies, having no risk factor for infertility, with infertile spouse. Exclusion

criteria: none.

Age

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

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Hamedan University of Medical Sciences

Street address

Hamedan University Of Medical Sciences & Health Services

City

Hamedan

Postal code

Approval date

2011-11-19, 1390/08/28

Ethics committee reference number

2860/35/16/د/پ

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N46

ICD-10 code description

Male infertility

2

Description of health condition studied

Infertility

ICD-10 code

N50.0

ICD-10 code description

Atrophy of testis

3

Description of health condition studied

infertility

ICD-10 code

N50.8

ICD-10 code description

Other specified disorders of male genital organs

4

Description of health condition studied

infertility

ICD-10 code

N97.4

ICD-10 code description

Female infertility associated with male factors

Primary outcomes

1

Description

Number of dominant follicle

Timepoint

The day in which there are seen at least 2 follicles with the sizes 17-18 cm

Method of measurement

Repeating sonography every 2 days from the date of starting induction till ripping follicle having the foregoing particulars

2

Description

Number of eggs in third day of fertilization

Timepoint

Third day of fertilization

Method of measurement

counting

3

Description

Number of positive clinical pregnancy

Timepoint

16 day after embryo transfer

Method of measurement

laboratory

4

Description

Number of induction days

Timepoint

From the date of starting till injection of HCG ampoule

Method of measurement

counting

5

Description

Cost of drugs

Timepoint

From the date of starting till injection of HCG ampoule

Method of measurement

total drug costs

6

Description

Number of punctured ovum

Timepoint

Immediately after puncture

Method of measurement

counting

Secondary outcomes

1

Description

Incidence of OHSS

Timepoint

3-5 day after puncture

Method of measurement

sign- sonography-lab

Intervention groups

1

Description

Control group: starting Buserelin from the 21th day of previous cycle, daily 50 units and then it shall be decreased from the third day of cycle daily 20 units starting Gonal-F; continuing the process till formation of at least 2 follicles sized 17-18 cm and several follicles sized 14-16 cm; then injecting HCG.

Category

Treatment - Drugs

2

Description

Intervention group: from the 3rd day of cycle, Gonal-F is applied and from the 8th day injecting Cetrotide ampoule dosage 0.25 mg daily, till reaching the mentioned size of follicle in agonist group; then stopping stimuli and injecting HCG ampoule.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility unit of Fatemieh Hospital

Full name of responsible person

Maryam Hedayat, M.D.

Street address

Fatemieh Hospital, Kermanshah Ave.

City

Hamedan

2

Recruitment center

Name of recruitment center

Infertility unit of Taleghani Hospital

Full name of responsible person

Maryam Hedayt, M.D.

Street address

Parvaneh St., Yaman St., Velenjak, Chamran expressway

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Haydar Tavilani, M.D.

Street address

Vice chancellor for research, Hamedan University, Fahmide St., Besat exprssway

City

Hamedan

Grant name

10506000 [جاري تحقيقات]

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Hamedan University Of Medical Sciences

Full name of responsible person

Maryam Hedayat, M.D.

Position

Gynecologist and Obstetrics Assistant

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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