

# 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)

##### Phone

+98 81 1838 0572

##### Email address

maryam.hedayat@umsha.ac.ir

##### 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

**Other areas of specialty/work****Street address**

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**Full name of responsible person**

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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*