

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Efficacy of low-dose hCG adjunct to r-hFSH plus GnRH antagonist for ovarian stimulation in assisted reproductive technology

#### Protocol summary

##### Summary

The aim of this study is to evaluate the effect of adding low-dose hCG to GnRH antagonist+r-hFSH protocols on the outcome of ART in the patients undergoing IVF/ICSI cycle. This study is a clinical trial. In all 120 patients pre-treatment with OCP will be given during the cycle prior to the IVF/ICSI. r-hFSH (150-300 IU) will be loaded on either day 2 or 3 of the menstrual cycle, and the full dose will be continued until two follicles reach 14-15 mm in size, then daily administration of 0.25 mg of cetrorelix will be started. The starting dose of FSH will be chosen according to patient's age, BMI, and ovarian responsiveness in previous cycle. according to the study group, patients will receive or will not, a daily injection of hCG (200 IU). when at least 2 follicles reach 18 mm in size, 10000 IU of hCG will be injected and oocyte retrieval will be performed within 35-36 hours. After that, All patients will undergo an ICSI procedure. Luteal phase will be started on the day of oocyte retrieval by vaginal administration of cyclogest 400 mg/day. BhCG will be checked 15 days after oocyte retrieval and pregnancy will be confirmed by pregnancy sac visualization by week 6. Serum E2 level on the day of hCG administration, number of total oocytes, number of mature oocyte, FSH total dose, duration of stimulation, number of good quality embryo, fertilization and pregnancy rate will be compared between two groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201211197165N2**  
Registration date: **2012-11-25, 1391/09/05**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-11-25, 1391/09/05

##### Registrant information

###### Name

Ladan Kashani

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8828 1866

###### Email address

kashani\_ladan@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Tehran University of Medical Sciences

##### Expected recruitment start date

2012-11-21, 1391/09/01

##### Expected recruitment end date

2013-02-21, 1391/12/03

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Efficacy of low-dose hCG adjunct to r-hFSH plus GnRH antagonist for ovarian stimulation in assisted reproductive technology

##### Public title

Efficacy of low-dose hCG adjunct to r-hFSH plus GnRH antagonist for ovarian stimulation in assisted reproductive technology

##### Purpose

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: infertile female patient; age between 20-39 years old; body mass index(BMI) of 20- 25 kg/m2; a normal uterus and two functional ovaries; day 3 FSH level< 10 IU/L and E2 level< 60 pg/ml.Exclusion criteria: history of > 2 unsuccessful IVF/ICSI attempts; poor ovarian response in previous IVF/ICSI treatment and any endocrine disorders.

### **Age**

From **20 years** old to **39 years** old

### **Gender**

Female

### **Phase**

2

### **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**

Ethic Committee of Tehran University of Medical Sciences

##### **Street address**

Ethic Committee of Tehran University of Medical Sciences, 16 azar avenue, Keshavarz bolvar

##### **City**

Tehran

##### **Postal code**

##### **Approval date**

2007-04-25, 1386/02/05

##### **Ethics committee reference number**

5739

## **Health conditions studied**

### 1

#### **Description of health condition studied**

infertility

#### **ICD-10 code**

N97

### **ICD-10 code description**

Female infertility associated with anovulation

## **Primary outcomes**

### 1

#### **Description**

Beta-hCG level

#### **Timepoint**

15 days after oocyte retrieval

#### **Method of measurement**

By laboratory kit from blood sample

## **Secondary outcomes**

### 1

#### **Description**

Number of mature oocytes

#### **Timepoint**

35-36 hours after high-dose hCG injection

#### **Method of measurement**

Transabdominal ultrasound

## **Intervention groups**

### 1

#### **Description**

r-hFSH + GnRH antagonist

#### **Category**

Treatment - Drugs

### 2

#### **Description**

r-hFSH + GnRH antagonist + low-dose hCG

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Arash Hospital

##### **Full name of responsible person**

Dr. Ladan Kashani

##### **Street address**

Tehran Pars, Rashid Street, Arash Hospital

##### **City**

Tehran

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

**Name of organization / entity**

Vice Chancellor for Research, Tehran University of  
Medical Sciences

**Full name of responsible person**

Dr. Akbar Foutohi

**Street address**

Tehran University of Medical Sciences, Keshavarz  
Blvd

**City**

Tehran

**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, Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Ladan Kashani

**Position**

Assistant Prof.

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

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**Fax****Email**

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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*