

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of intra-uterine hCG injection versus placebo in improving implantation in women fertilized with IVF method: a randomized clinical trial

#### Protocol summary

##### Summary

Objectives: To assess the effect intra-uterine hCG injection versus placebo in improving implantation in women fertilized with IVF method. Design: a randomized clinical trial. Setting and conduct: The eligible women fertilized with IVF method who will refer to Fatemieh Hospital during the study period will be enrolled into the trial. Inclusion criteria: age of 18 to 40 years; the cause of infertility is male sex. Exclusion criteria: using OCP or any kind of hormonal products before IVF; azoospermia; having myoma or history of myomectomy; endometriosis. Intervention group: Intra-uterine hCG injection 500 U single dose. Control group: Without injection. Primary outcome: (a) assessing pregnancy 2 weeks after intervention using pregnancy test; (b) assessing pregnancy sock 3 weeks after intervention using ultrasonography. Secondary outcome: Assessing abortion before 20 weeks of pregnancy with taking history. Randomization: Random assignment of the patients to the intervention and control groups one at a time. Blinding: Not blinded.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201510079014N81**

Registration date: **2015-10-20, 1394/07/28**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2015-10-20, 1394/07/28

##### Registrant information

Name

Jalal Poorolajal

##### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 1838 0090

##### Email address

poorolajal@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

##### Expected recruitment start date

2015-10-23, 1394/08/01

##### Expected recruitment end date

2016-10-21, 1395/07/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of intra-uterine hCG injection versus placebo in improving implantation in women fertilized with IVF method: a randomized clinical trial

##### Public title

Effect of intra-uterine hCG injection versus placebo in improving implantation in women fertilized with IVF method

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: age of 18 to 40 years; the cause of infertility is male sex. Exclusion criteria: using OCP or any kind of hormonal products before IVF; azoospermia; having myoma or history of myomectomy; endometriosis.

#### **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: **90**

#### **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**

Ethics Committee of Hamadan University of Medical Sciences

###### **Street address**

Vice-chancellor for Research the Technology,  
Hamadan University of Medical Sciences, Shahid  
Fahmideh Ave

###### **City**

Hamadan

###### **Postal code**

6517838695

###### **Approval date**

2015-05-26, 1394/03/05

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

IR.UMSHA.REC.1394.70

### **Health conditions studied**

#### **1**

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

Infertility

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

N97

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

Female infertility

### **Primary outcomes**

#### **1**

##### **Description**

assessing pregnancy

##### **Timepoint**

2 weeks after intervention

##### **Method of measurement**

using pregnancy test

#### **2**

##### **Description**

assessing pregnancy sock

##### **Timepoint**

3 weeks after intervention

##### **Method of measurement**

using ultrasonography

### **Secondary outcomes**

#### **1**

##### **Description**

Assessing abortion

##### **Timepoint**

before 20 weeks of pregnancy

##### **Method of measurement**

with taking history

### **Intervention groups**

#### **1**

##### **Description**

Intra-uterine hCG injection 500 U single dose

##### **Category**

Treatment - Drugs

#### **2**

##### **Description**

Without injection

##### **Category**

N/A

### **Recruitment centers**

#### **1**

##### **Recruitment center**

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

Fatemieh Hospital

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

Dr Sima Saffary

###### **Street address**

Fatemieh Hospital, Pasdaran Ave.

###### **City**

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice-chancellor for Research the Technology,  
Hamadan University of Medical Sciences

**Full name of responsible person**

Dr Saeid Bashirian

**Street address**

Hamadan University of Medical Sciences, Shahid  
Fahmideh Ave

**City**

Hamadan

**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 the Technology, Hamadan  
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**

Fatemieh Hospital

**Full name of responsible person**

Dr Sima Saffary

**Position**

Resident of Gynecology

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

Fatemieh Hospital, Pasdaran Ave.

**City**

Hamadan

**Postal code****Phone**

+98 81 3828 3939

**Fax****Email**

simasaffary@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Fatemieh Hospital

**Full name of responsible person**

Dr Soghra Rabiee

**Position**

Gynecologist

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

Fatemieh Hospital, Pasdaran Ave.

**City**

Hamadan

**Postal code****Phone**

+98 81 3828 3939

**Fax****Email**

rebieeso@yahoo.com

**Web page address**

## Person responsible for updating data

**Contact****Name of organization / entity**

Department of Epidemiology

**Full name of responsible person**

Dr Jalal Poorolajal

**Position**

Associate Professor

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

School of Public Health, Hamadan University of  
Medical Sciences, Shahid Fahmideh Ave

**City**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0090

**Fax****Email**

poorolajal@umsha.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*