

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### The effect of adding low dose human Chorionic Gonadotropin (hCG) to recombinant Follicular Stimulating Hormone (rFSH) on follicular phase in women undergoing intracytoplasmic sperm injection cycle, a clinical trial.

#### Protocol summary

##### Summary

This research is done to examine the effect of adding low dose human Chorionic Gonadotropin (hCG) to recombinant Follicular Stimulating Hormone (rFSH) on follicular phase in women undergoing intracytoplasmic sperm injection cycle. This research is randomized double blind controlled clinical trial. Our trial performs in Fateme Zahra Reproductive Research Center in Babol, Iran. Patients with these inclusion criteria: 20 – 40 years old; normal salpingography are selected and randomly divided in three groups. Exclusion criteria include history of previous chronic disease. Patients randomly placed in to three groups of 50 women. In all three groups all patients treated with a dose of 150 International Unit (IU) rFSH per day. In the first group or control group treatment with rFSH will continue until the creation of the oocytes. In the second group when the follicle size become 14 millimeter, rFSH dose reduce to 75 IU per day and treatment starts with 100 IU hCG per day. In the third group when follicle size become 14 millimeter, treatment with rFSH stops and patient treat with 200 IU hCG per day. Gonadotropin administration continues to mature follicles. When at least two or three follicles 18 millimeter to 20 millimeter in size were formed; 100 IU hCG will inject. Thirty six hours later ovarian puncture is performed. Oocyte maturation, ovarian hyperstimulation syndrome and follicular response will compare in three groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017012932284N1**

Registration date: **2017-03-07, 1395/12/17**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-03-07, 1395/12/17

##### Registrant information

###### Name

Maryam Yeganegi

###### Name of organization / entity

Babol Univerisity of Medical Science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 11 3230 3113

###### Email address

m.yeganegi@mubabol.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Babol University of Medical Sciences.

##### Expected recruitment start date

2017-02-19, 1395/12/01

##### Expected recruitment end date

2017-06-22, 1396/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of adding low dose human Chorionic Gonadotropin (hCG) to recombinant Follicular Stimulating Hormone (rFSH) on follicular phase in women undergoing intracytoplasmic sperm injection cycle, a clinical trial.

##### Public title

Effect of human Chorionic Gonadotropin (hCG) on treatment of infertility

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

Inclusion Criteria: 20 - 40 years old; 1 year history of infertility; candidate for intracytoplasmic sperm injection.

Exclusion Criteria: history of chronic disease; abnormal salpingography.

### **Age**

From **20 years** old to **40 years** old

### **Gender**

Female

### **Phase**

3

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **150**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Double blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Other

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Babol University of Medical Sciences

##### **Street address**

Rohani hospital, Ganjafrooz street, Babol

##### **City**

Babol

##### **Postal code**

4717647745

#### **Approval date**

2016-07-13, 1395/04/23

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

mubabol.hri.rec.1395.54

## **Health conditions studied**

### 1

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

Infertility

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

n97.0

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

Female infertility associated with anovulation

## **Primary outcomes**

### 1

#### **Description**

Follicle size

#### **Timepoint**

Daily

#### **Method of measurement**

Ultrasonography - Milimeter

### 2

#### **Description**

Mature oocyte

#### **Timepoint**

End of Cycle

#### **Method of measurement**

Sonography

## **Secondary outcomes**

### 1

#### **Description**

Ovarian Hyperstimulation Syndrome

#### **Timepoint**

Daily

#### **Method of measurement**

Sonography - Follicle size - Milimeter

## **Intervention groups**

### 1

#### **Description**

In the first group patients treated with a dose of 150 International Unit (IU) recombinant Follicular Stimulating Hormone (rFSH) per day. Treatment with rFSH will continue until the creation of the oocytes. When at least two or three follicles 18 millimeter to 20 millimeter in size were formed; 100 IU human Chorionic Gonadotropin (hCG) will inject. Thirty six hours later ovarian puncture is performed

#### **Category**

Treatment - Drugs

### 2

#### **Description**

In the second group patients treated with a dose of 150 International Unit (IU) recombinant Follicular Stimulating Hormone (rFSH) per day. When the follicle size become 14 millimeter, rFSH dose reduce to 75 IU per day and treatment starts with 100 IU human Chorionic Gonadotropin (hCG) per day. When at least two or three follicles 18 millimeter to 20 millimeter in size were formed; 100 IU hCG will inject. Thirty six hours later ovarian puncture is performed.

**Category**

Treatment - Drugs

**3****Description**

In the third group patients treated with a dose of 150 International Unit (IU) recombinant Follicular Stimulating Hormone (rFSH) per day. When follicle size become 14 millimeter, treatment with rFSH stops and patient treat with 200 IU human Chorionic Gonadotropin per day. When at least two or three follicles 18 millimeter to 20 millimeter in size were formed; 100 IU hCG will inject. Thirty six hours later ovarian puncture is performed.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Fatemehzahra Infertility and Reproductive Health Research Center

**Full name of responsible person**

Dr. Maryam Yeganegi

**Street address**

Torkmahalle, 3 Km after Mohammad Hassan Khan Bridge, Babol, Mazandaran,Iran

**City**

Babol

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice Chancellor for Research, Babol University of Medical Science

**Full name of responsible person**

Dr Ali Bijani

**Street address**

Babol University of Medical Science, Ganjafrooz Street,

**City**

Babol

**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, Babol University of Medical Science

**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**

Babol University of Medical Science

**Full name of responsible person**

Dr Maryam Yeganegi

**Position**

Resident of Gynecology

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

Rohani Hospital, Ganjafrooz Street, Babol

**City**

Babol

**Postal code****Phone**

+98 11 3227 4880

**Fax****Email**

parastoo0847@yahoo.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Babol University of Medical Science

**Full name of responsible person**

Dr Zahra Basirat

**Position**

Professor of Gynecology

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

Rohani Hospital, Ganjafrooz Street, Babol

**City**

Babol

**Postal code****Phone**

+98 11 3223 8267

**Fax****Email**

basiratzahra@yahoo.com

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Babol University of Medical Science

**Full name of responsible person**

Dr Maryam Yeganegi

**Position**

Resident of Gynecology

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

Rohani Hospital, Ganjafrooz street, Babol

**City**

Babol

**Postal code**

**Phone**

+98 11 3223 8267

**Fax**

**Email**

parastoo0847@yahoo.com

**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*