

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### The effect of recombinant follicle-stimulating hormone (rFSH) on semen parameters after varicocelelectomy in infertile men referring to the Comprehensive Women's Hospital (Mohebe-Yas) since September 2014 to September 2015

#### Protocol summary

##### Summary

This study is an interventional, randomized clinical trial. The purpose of this study was to evaluate the effects of rFSH on semen parameters after varicocelelectomy in infertile men. Infertile men who referred to Mohebe-Yas hospital and undergoing varicocelelectomy were enrolled to this study Conveniently. Semen parameters were measured for all patients. The patients were randomly divided into two groups. One group was treated with subcutaneous Recombinant FSH and the second group received placebo with the same method. Treatment was done 3 times a week for a period of 3 months. After 3 months, the rate of improvement in semen parameters including Motility, morphology, and Count and side effects were determined and compared in both groups. Finally data were statistically analyzed by SPSS version 13.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015061522757N1**  
Registration date: **2015-06-22, 1394/04/01**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-06-22, 1394/04/01

##### Registrant information

##### Name

Atoosa Bagheri behzad

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4216 0852

##### Email address

atoosa.bagheribehzad@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of Medical Sciences

##### Expected recruitment start date

2014-09-23, 1393/07/01

##### Expected recruitment end date

2015-09-21, 1394/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of recombinant follicle-stimulating hormone (rFSH) on semen parameters after varicocelelectomy in infertile men referring to the Comprehensive Women's Hospital (Mohebe-Yas) since September 2014 to September 2015

##### Public title

Effect of Recombinant FSH on infertility

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: varicocelelectomy for unilateral idiopathic varicocele; Age 20 to 40 years; patient consent Exclusion criteria: lack of consent; being allergic

to pharmaceutical composition

### Age

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

### Gender

Male

### Phase

3

### Groups that have been masked

*No information*

### Sample size

Target sample size: **96**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Double blinded

### Blinding description

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Tehran University of medical sciences

##### Street address

14155 Poursina St- Keshavarz Blvd

##### City

Tehran

##### Postal code

14155-5583

#### Approval date

2015-01-03, 1393/10/13

#### Ethics committee reference number

9121290002-133624

## Health conditions studied

### 1

#### Description of health condition studied

Male Infertility

#### ICD-10 code

N46

#### ICD-10 code description

Male infertility

## Primary outcomes

### 1

#### Description

Sperm count

### Timepoint

After varicocelelectomy before treatment and 3 months after treatment

### Method of measurement

According semen analysis

### 2

#### Description

Sperm motility

#### Timepoint

After varicocelelectomy before treatment and 3 months after treatment

#### Method of measurement

According semen analysis

### 3

#### Description

Sperm morphology

#### Timepoint

After varicocelelectomy before treatment and 3 months after treatment

#### Method of measurement

According semen analysis

## Secondary outcomes

### 1

#### Description

Complications

#### Timepoint

During the three-month period of treatment

#### Method of measurement

According case history

## Intervention groups

### 1

#### Description

Injection Follitropin / Rcombinant FSH subcutaneously - 75 units / 0.5 ml in the intervention group

#### Category

Treatment - Drugs

### 2

#### Description

Injection Normal Saline subcutaneously - 0.5 ml in control group

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

Name of recruitment center

Mohebe-Yas hospital

**Full name of responsible person**

**Street address**

**City**

Tehran

## Sponsors / Funding sources

1

**Sponsor**

**Name of organization / entity**

Tehran university of medical sciences

**Full name of responsible person**

Dr. Mahbod Ebrahimi

**Street address**

14155 Poursina St- 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**

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. Atoosa Bagheri Behzad

**Position**

Resident of Obstetrics and Gynecology

**Other areas of specialty/work**

**Street address**

North Nejat-alahi St-Karim Khan zand Ave

**City**

Tehran

**Postal code**

**Phone**

+98 21 4216 0852

**Fax**

**Email**

Atoosa.bagheribehzad@yahoo.com

**Web page address**

## Person responsible for scientific

## inquiries

**Contact**

**Name of organization / entity**

Tehran university of medical sciences

**Full name of responsible person**

Dr. Mahbod Ebrahimi

**Position**

Fellowship of infertility

**Other areas of specialty/work**

**Street address**

North Nejat-alahi St-Karim Khan zand Ave

**City**

Tehran

**Postal code**

**Phone**

+98 21 4216 0852

**Fax**

**Email**

maeb@sina.tums.ac.ir

**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Tehran university off medical sciences

**Full name of responsible person**

Dr. Atoosa Bagheri Behzad

**Position**

Resident of Gynecology and Obstetrics

**Other areas of specialty/work**

**Street address**

North Nejat-alahi St-Karim Khan zand Ave

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## 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*