

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Comparison of the effects of treatment with recombinant human follicle stimulating hormone (rhFSH), human chorionic gonadotropin (HCG) and human menopausal gonadotropin (HMG) on semen parameters after varicocelectomy in patients with varicocele

#### Protocol summary

##### Summary

Our study aim, for the first time, to compare the efficacy of recombinant human follicle-stimulating hormone (rhFSH), human chorionic gonadotropin (HCG) and human menopausal gonadotropin (HMG) on sperm parameters and fertility after varicocelectomy. This study is designed as a multicenter, double blind, randomized clinical trial. the major inclusion criteria is male factor infertility due to varicocele and the major exclusion criteria are underlying testis abnormalities and abnormal reproductive hormone levels. One-hundred and twenty patients who will be referred to the Fertility and Infertility Research Center of Hamadan University of Medical Sciences and the Urology and Nephrology Research Center of Shahid Beheshti University of Medical Sciences will be divided into four groups considering the similarity and randomization to treat for three months with recombinant human follicle-stimulating hormone, human chorionic gonadotropin and human menopausal gonadotropin and no medical treatment after varicocelectomy. finally sperm parameters and fertility in all groups will be compared.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201112248509N1**

Registration date: **2012-01-06, 1390/10/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2012-01-06, 1390/10/16

#### Registrant information

##### Name

Nasibeh Amirzargar

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2264 0582

##### Email address

n-amirzargar@razi.tums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Urology and Nephrology Research Center of Shahid Beheshti University of Medical Sciences Fertility and Infertility Research Center of Hamadan University of Medical Sciences

#### Expected recruitment start date

2010-01-01, 1388/10/11

#### Expected recruitment end date

2011-01-01, 1389/10/11

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison of the effects of treatment with recombinant human follicle stimulating hormone (rhFSH), human chorionic gonadotropin (HCG) and human menopausal gonadotropin (HMG) on semen parameters after varicocelectomy in patients with varicocele

#### Public title

The effect of treatment with recombinant human follicle stimulating hormone (rhFSH), human chorionic gonadotropin (HCG) and human menopausal gonadotropin (HMG) on semen parameters after varicocele: a randomized clinical trial.

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: infertility after 12 months of unprotected intercourse; male factor infertility due to varicocele; spontaneous onset of maturation and normal sexual development Exclusion criteria: presence of infertility due to any other factor especially female infertility; systemic disease; underlying testis abnormalities; abnormal reproductive hormone levels.

**Age**

No age limit

**Gender**

Male

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 120

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Urology and Nephrology Research Center (UNRC),  
Shahid Labbafinejad Medical Center

**Street address**

labafinejad hospital

**City**

tehran

**Postal code****Approval date**

2007-06-23, 1386/04/02

**Ethics committee reference number**

م-ت-الف-118

**Health conditions studied****1****Description of health condition studied**

infertility

**ICD-10 code**

N46

**ICD-10 code description**

Male infertility

**Primary outcomes****1****Description**

sperm parameters

**Timepoint**

before initiation of treatment and further control examinations were performed 8 to 10 weeks after the completion of each period of treatment

**Method of measurement**

spermogram

**Secondary outcomes****1****Description**

pregnancy

**Timepoint**

6 month

**Method of measurement**

bHCG

**Intervention groups****1****Description**

Patients will be treated with 5000 IU human chorionic gonadotropin weekly intramuscular for 3 months.

**Category**

Treatment - Drugs

**2****Description**

Patients will be treated with 75 IU human menopausal gonadotropin three times a week sub cutaneous for 3 months.

**Category**

Treatment - Drugs

**3****Description**

Patients will be treated with 75 IU recombinant human follicle-stimulating hormone three times a week sub cutaneous for 3 months.

**Category**

Treatment - Drugs

#### 4

##### **Description**

no medical treatment after varicocelelectomy

##### **Category**

Treatment - Drugs

### **Recruitment centers**

#### 1

##### **Recruitment center**

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

Fertility and Infertility Research Center of Hamadan  
University of Medical Sciences

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

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

###### **City**

hamadan

#### 2

##### **Recruitment center**

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

Urology and Nephrology Research Center of Shahid  
Beheshti University of Medical Sciences

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

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

###### **City**

tehran

### **Sponsors / Funding sources**

#### 1

##### **Sponsor**

###### **Name of organization / entity**

Urology and Nephrology Research Center of Shahid  
Beheshti University of Medical Sciences

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

Abbass Basiri

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

Urology and Nephrology Research Center, Shahid  
Labbafinejad Medical Hospital, Pasdaran avenue,  
Tehran

###### **City**

tehran

###### **Grant name**

###### **Grant code / Reference number**

###### **Is the source of funding the same sponsor organization/entity?**

Yes

###### **Title of funding source**

Urology and Nephrology Research Center of Shahid  
Beheshti University of Medical Sciences

###### **Proportion provided by this source**

###### **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*

#### 2

##### **Sponsor**

###### **Name of organization / entity**

Hamadan University of Medical Sciences

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

Mohammad Ali Amirzargar

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

Urology Department, Hamadan University of Medical  
Sciences, University square, Hamadan

###### **City**

Hamadan

###### **Grant name**

###### **Grant code / Reference number**

###### **Is the source of funding the same sponsor organization/entity?**

Yes

###### **Title of funding source**

Hamadan University of Medical Sciences

###### **Proportion provided by this source**

###### **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**

Department of Urology, Hamadan University of  
Medical Sciences

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

Mohammad Ali Amirzargar

###### **Position**

urologist

###### **Other areas of specialty/work**

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### **Person responsible for scientific inquiries**

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Mohammad Ali Amirzargar

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Sciences, University square, Hamadan

**City****Postal code****Phone**

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**Fax****Email****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*