Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of recombinant follicle-stimulating hormone (rFSH) on semen parameters after varicocelectomy 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 varicocelectomy in infertile men. Infertile men who referred to Moheb-Yas hospital and undergoing varicocelectomy 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

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Name of organization / entity

Tehran University of Medical Sciences

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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 varicocelectomy 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: varicocelectomy 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 siences

Street address

14155 Poursina St- Keshavarz Blvd

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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 varicocelectomy before treatment and 3 months after treatment

Method of measurement

According semen analusis

2

Description

Sperm motility

Timepoint

After varicocelectomy before treatment and 3 months after treatment

Method of measurement

According semen analusis

3

Description

Sperm morphology

Timepoint

After varicocelectomy before treatment and 3 months after treatment

Method of measurement

According semen analusis

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

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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