Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of treatment with HCG and recombinant human FSH versus not treatment on improvement of semen parameters in infertile men after surgical repair of varicocele: a randomized clinical trial

Protocol summary

Summary

Objectives: To compare the effect of treatment with HCG and recombinant human FSH on improvement of semen parameters in infertile men after surgical repair of varicocele. Design:A randomized clinical trial. Setting and conduct:All infertile females who will refer to infertility clinics of Hamadan City during 2012 and 2013. Participants including major eligibility criteria: The inclusion criteria are: (a) having unilateral or bilateral palpable varicocele; (b) history of infertility for at least one-year; (c) having healthy wife; having abnormal spermogram. The exclusion criteria are: (a) having no testis in scrotum; (b) having acute urogenital infection; (c) medical history of abnormal function of testis such as: trauma, torsion, cryptorchidism, vas deferens obstruction, abnormal karyotype, diabetes, chemotherapy, any history of surgical treatment on testis, scrotum or pituitary gland; (d) contraindication of FSH such as high level of FSH in serum or uncontrolled dysfunction of thyroid or adrenal glands; (e) BMI>40; (f) substance abuse such as alcohol, narcotics, or anabolic asteroids; (g) testis smaller than 4 mL in ultrasonography; (h) azoospermia (no spermatozoid); (i) using gonadotropin. Intervention:The intervention group will be undergone varicocelectomy and then will receive 75 IU recombinant human FSH subcutaneously three times a week and 5000 IU HCG intramuscularly once a week for three months. The control group will be undergone varicocelectomy only. Main outcome measures: The outcome of interest is improvement of the semen parameters including concentration (106/mm2), motility (%), and morphology (%) of spermatozoid after three months as well as the increase in the rate of pregnancy and decrease in the duration of waiting time for pregnancy after one year.

General information

Acronym

HCG: Human Chorionic Gonadotropin FSH: Follicle Stimulating Hormone

IRCT registration information

IRCT registration number: **IRCT201203039014N3**
Registration date: **2012-04-25, 1391/02/06**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-04-25, 1391/02/06

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

Vic-chancellor of Research and Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2012-05-21, 1391/03/01

Expected recruitment end date

2013-05-21, 1392/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of treatment with HCG and recombinant human FSH versus not treatment on improvement of semen parameters in infertile men after surgical repair of varicocele: a randomized clinical trial

Public title

Comparison of the effect of treatment with HCG and recombinant human FSH versus not treatment on improvement of semen parameters in infertile men after surgical repair of varicocele

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria are: (a) having unilateral or bilateral palpable varicocele; (b) history of infertility for at least one-year; (c) having healthy wife; having abnormal spermogram. Exclusion criteria are: (a) having no testis in scrotum; (b) having acute urogenital infection; (c) medical history of abnormal function of testis such as: trauma, torsion, cryptorchidism, vas deferens obstruction, abnormal karyotype, diabetes, chemotherapy, any history of surgical treatment on testis, scrotum or pituitary gland; (d) contraindication of FSH such as high level of FSH in serum or uncontrolled dysfunction of thyroid or adrenal glands; (e) BMI>40; (f) substance abuse such as alcohol, narcotics, or anabolic asteroids; (g) testis smaller than 4 mL in ultrasonography; (h) azoospermia (no spermatozoid); (i) using gonadotropin.

Age

No age limit

Gender

Male

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **94**

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

Local Human Subject Review board

Street address

Hamadan University of Medical Sciences, Shaheed Fahmideh Ave.

City

Hamadan

Postal code

6517838695

Approval date

2012-04-22, 1391/02/03

Ethics committee reference number

D/P/16/35/9/246

Health conditions studied

1

Description of health condition studied

Male infertility due to varicocele

ICD-10 code

N46

ICD-10 code description

Male infertility

Primary outcomes

1

Description

The outcome of interest is improvement of the semen parameters including concentration (106/mm2), motility (%), and morphology (%) of spermatozoid.

Timepoint

Three months

Method of measurement

Laboratory tests

Secondary outcomes

1

Description

The secondary outcome of interest is the increase in the rate of pregnancy and decrease in the duration of waiting time for pregnancy.

Timepoint

One year

Method of measurement

History taking

Intervention groups

1

Description

The intervention group will be undergone varicocelectomy and then will receive 75 IU recombinant human FSH subcutaneously three times a week and 5000 IU HCG intramuscularly once a week for three months.

Category

Treatment - Drugs

2

Description

The control group will be undergone varicocelectomy only without hormone therapy.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Beasat Hospitals

Full name of responsible person

Dr Mohammad Ali Amirzargar

Street address

Shahed Ave.

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vic-Chancellor of Research and Technology, Hamadan University of Medical Sciences

Full name of responsible person

Ahmad Tavilani

Street address

Hamadan University of Medical Sciences, Shaheed Fahmideh Ave

City

Hamadan

Grant name

از محل يك درصد بودجه طرح‌هاي تحقيقاتي دانشگاه

Grant code / Reference number

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

Yes

Title of funding source

Vic-Chancellor of Research and 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

Research Center for Health Sciences, Department of Epidemiology & Biostatistics

Full name of responsible person

Dr Jalal Poorolajal

Position

MD, PhD, Assistant Professor of Epidemiology

Other areas of specialty/work

Street address

School of Public Health, Hamadan University of Medical Sciences, Shaheed Fahmideh Ave.

City

Hamadan

Postal code

6517838695

Phone

+98 81 1838 0090

Fax

+98 81 1838 0509

Email

poorolajal@umsha.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Department of Urology, School of Medicine

Full name of responsible person

Dr Mohammad Ali Amirzargar

Position

MD, Assistant Professor of Urology

Other areas of specialty/work

Street address

Hamadan University of Medical Sciences, Shaheed Fahmideh Ave

City

Hamadan

Postal code

6517838695

Phone

Fax

Email

dr_amirzargar@yahoo.com

Web page address

Person responsible for updating data

Contact

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