

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Randomised clinical assessment of varicocele treatment outcomes with gubernacular veins closure

Protocol summary

Summary

Objectives: Comparison of standard inguinal varicocele treatment and varicocele treatment with gubernacular veins closure in severe varicocele treatment based on age, infertility time, and unilateral or bilateral surgery
Planning: Controlled randomized one-side blinded trial
Method: 78 patients with severe varicocele (based on physical exam and sonography) who admitted in Shohada-e Tajrish Medical Center allocated in one the case or control groups. Inclusion criterion: men with severe varicocele. Exclusion criteria: infertility due to other causes; chronic comorbidities such as diabetes mellitus and other endocrinologic disorders; atrophic testes; past history of surgical procedures relating to genitalia. Interventions: Intervention group: Closure of varicose veins via inguinal approach and then delivering of testis outside of the scrotum via the same inguinal wound and closure of gubernacular veins and then replacement of testis into the scrotum Control group: Standard varicocele treatment. it means closure of varicose veins via inguinal approach Primary outcome measures: Semen count, Normal morphology rate in sperms, and Sperm motility rate 6 months after procedure

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016092524166N2**

Registration date: **2016-11-29, 1395/09/09**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-11-29, 1395/09/09

Registrant information

Name

Hamidreza Qashqai

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 912 230 7789

Email address

qashqae@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

LASER Application in Medical Sciences Research Center, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2016-05-01, 1395/02/12

Expected recruitment end date

2016-11-30, 1395/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomised clinical assessment of varicocele treatment outcomes with gubernacular veins closure

Public title

Comparative assessment of varicocele treatment outcomes with and without gubernacular veins closure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criterion: men with severe varicocele. Exclusion criteria: infertility due to other causes; chronic comorbidities such as diabetes mellitus and other endocrinologic disorders; atrophic testes; past history of

surgical procedures relating to genitalia.

Age

From **15 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **78**

Randomization (investigator's opinion)

Randomized

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

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Shahid Beheshti university of medical sciences

Street address

Velenjak

City

Tehran

Postal code**Approval date**

2016-03-07, 1394/12/17

Ethics committee reference number

IR.SBMU.RETECH.REC.1395.185

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

Scrotal varices (Varicocele)

ICD-10 code

186.1

ICD-10 code description

Varicocele

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

Semen count

Timepoint

six months after surgical procedure

Method of measurement

Semen analysis

2**Description**

Normal morphology rate in sperms

Timepoint

six months after surgical procedure

Method of measurement

Semen analysis

3**Description**

Sperm motility rate

Timepoint

six months after surgical procedure

Method of measurement

Semen analysis

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

Procedure Failure

Timepoint

Six months after procedure

Method of measurement

Sperm analysis

2**Description**

Operation side effects such as hemorrhage, infection and relapse of varicocele

Timepoint

1 month after procedure, 3 months after procedure and 6 months after procedure

Method of measurement

Physical examination

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

Intervention group: Closure of varicose veins via inguinal approach and then delivering of testis outside of the scrotum via the same inguinal wound and closure of gubernacular veins and then replacement of testis into the scrotum

Category

Treatment - Surgery

2**Description**

Control group: Standard varicocelectomy. It means

closure of varicose veins via inguinal approach
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Shohada-e Tajrish Medical Center
Full name of responsible person
Dr. Farzad Allameh
Street address
Qods sq., Tajrish
City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
LASER Application in Medical Sciences Research
Center of Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Mohammadreza Razzaghi
Street address
Shohada-e Tajrish Medical Center, Qods sq.
City
Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

LASER Application in Medical Sciences Research Center
of Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Hamidreza Qashqai
Position
Urology Resident
Other areas of specialty/work

Street address

Shohada-e Tajrish Medical Center

City

Tehran

Postal code

Phone

+98 912 230 7789

Fax

Email

qashqaee@sbmu.ac.ir; qashqaee@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Farzad Allameh

Position

Urologist

Other areas of specialty/work

Street address

Shohada-e Tajrish Medical Center, Qods sq.

City

Tehran

Postal code

Phone

+98 912 388 5545

Fax

Email

farzadallame@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences,
Urology Department

Full name of responsible person

Dr. Hamidreza Qashqai

Position

Urology resident

Other areas of specialty/work

Street address

Shohada-e Tajrish Medical Center, Qods sq., Tajrish

City

Tehran

Postal code

Phone

00

Fax

Email

qashqaee@sbmu.ac.ir; qashqaee@gmail.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