Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Nov 2026

Randomised clinical assessment of varicocelectomy outcomes with gubernacular veins closure

Protocol summary

Summary

Objectives: Comparison of standard inguinal varicocelectomy and varicocelectomy 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 melitus 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: Satndard varicocelectomy. 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
qashqaee@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 varicocelectomy outcomes with gubernacular veins closure

Public title

Comparative assessment of varicocelectomy outcomes with and without gubernacular veins closure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criterion: men with sever varicocele. Exclusion criteria: infertility due to other causes; chronic comorbidities such as diabetes melitus 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: Satndard 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 Scien

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 Scien

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