

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Effect of laparoscopy versus open surgery on the size and function of testis in patients with varicocele: a double blinded randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of laparoscopy versus open surgery on the size and function of testis in patients with varicocele. **Design:** a double blinded randomized clinical trial. **Setting and conduct:** All eligible patients who are candidate for varicocelectomy and will refer to the Alvand Surgery Clinic or Motahary Hospital during the study period will be enrolled in to the trial. **Inclusion criteria:** (a); Patients with obvious unilateral or bilateral varicocele; (b) candidate for varicocelectomy. **Exclusion criteria:** (a) history of inguinal herniorrhaphy of the same side; (b) history of orchiopexy of the same side. **Intervention:** varicocelectomy using laparoscopy through under nipple. **Control:** varicocelectomy using open surgery with high ligation method. **Primary outcome:** (a) measuring testis size in ml before and 6 months after surgery using a pair of calipers; (b) semen analysis (number of sperm per mm³, sperm motility in percent, sperm morphology in percent) before and 6 months after surgery through laboratory methods. **Secondary outcome:** (a) hydrocele, edema, and hematoma of testis one week after surgery through physical examination; (b) recurrence of varicocele 6 months after surgery through physical examination.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201409299014N43**
Registration date: **2014-10-07, 1393/07/15**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-10-07, 1393/07/15

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

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University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan
University of Medical Sciences

Expected recruitment start date

2012-11-22, 1391/09/02

Expected recruitment end date

2013-10-24, 1392/08/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of laparoscopy versus open surgery on the size and function of testis in patients with varicocele: a double blinded randomized clinical trial

Public title

Effect of laparoscopy versus open surgery on the size and function of testis in patients with varicocele

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: (a); Patients with obvious unilateral or bilateral varicocele; (b) candidate for varicolectomy.
Exclusion criteria: (a) history of inguinal herniorrhaphy of the same side; (b) history of orchiopexy of the same side.

Age

No age limit

Gender

Male

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 48

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization: The patients will be randomly assigned to intervention and control group using paper sheets labeled surgery or laparoscopy. Blinding: non-blinded.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethic Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor of Research the Technology,
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Postal code

6517838695

Approval date

2012-11-22, 1391/09/02

Ethics committee reference number

D/P/16/35/9/3042

Health conditions studied

1

Description of health condition studied

varicocele

ICD-10 code

I86.1

ICD-10 code description

Scrotal varices

Primary outcomes

1

Description

measuring testis

Timepoint

size in ml before and 6 months after surgery

Method of measurement

using a pair of calipers

2

Description

semen analysis (number of sperm per mm³, sperm motility in percent, sperm morphology in percent)

Timepoint

before and 6 months after surgery

Method of measurement

through laboratory methods.

Secondary outcomes

1

Description

hydrocele, edema, and hematoma of testis

Timepoint

one week after surgery

Method of measurement

through physical examination

2

Description

recurrence of varicocele

Timepoint

6 months after surgery

Method of measurement

through physical examination

Intervention groups

1

Description

varicolectomy using laparoscopy through under nipple.

Category

Treatment - Surgery

2

Description

varicolectomy using open surgery with high ligation method

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Alvand Surgery Center

Full name of responsible person

Dr Marzieh Zaree

Street address

Alvand Surgery Center, Mahdiah Ave.

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

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Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-chancellor for Research the 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

Alvand Surgery Center

Full name of responsible person

Dr Marzieh Zaree

Position

Resident of Urology

Other areas of specialty/work

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Person responsible for scientific inquiries

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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