

# 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 mm<sup>3</sup>, 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

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

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 varicocelectomy.  
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 mm<sup>3</sup>, 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

varicocelectomy using laparoscopy through under nipple.

#### Category

Treatment - Surgery

### 2

#### Description

varicocelectomy 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

**Street address**

Hamadan University of Medical Sciences, Shahid  
Fahmideh Ave

**City**

Hamadan

**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**

**Street address**

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**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Alvand Surgery Center

**Full name of responsible person**

Dr Manoochehr Ghorbanpoor

**Position**

Urologist

**Other areas of specialty/work**

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**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*