

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of varicocelectomy with and without inguinal herniorrhaphy on scrotal pain in patients with varicocele: a single blind randomized clinical trial

#### Protocol summary

##### Summary

Objectives: To assess the effect of varicocelectomy with and without inguinal herniorrhaphy on scrotal pain in patients with varicocele. Design: a single blind randomized clinical trial. Setting and conduct: The eligible patients with painful varicocele who will refer to Shahid Beheshti Hospital during the study period will be enrolled into the trial. Inclusion criteria: (a) age of 18 to 65 years; (b) candidate for varicocelectomy. Exclusion criteria: (a) varicocele without pain; (b) any contraindication for varicocelectomy or herniorrhaphy. Intervention: varicocelectomy with inguinal herniorrhaphy. Control: varicocelectomy without inguinal herniorrhaphy. Primary outcome: measuring the pain severity one week, one month, and three months after surgery using VAS scale. Secondary outcome: Nothing.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201504089014N60**  
Registration date: **2015-04-25, 1394/02/05**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-04-25, 1394/02/05

##### 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

2015-04-04, 1394/01/15

##### Expected recruitment end date

2017-09-23, 1396/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of varicocelectomy with and without inguinal  
herniorrhaphy on scrotal pain in patients with varicocele:  
a single blind randomized clinical trial

##### Public title

Effect of varicocelectomy with and without inguinal  
herniorrhaphy on scrotal pain in patients with varicocele

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: (a) age of 18 to 65 years; (b) candidate  
for varicocelectomy. Exclusion criteria: (a) varicocele  
without pain; (b) any contraindication for  
varicocelectomy or herniorrhaphy.

##### Age

From **1 year** old to **65 years** old

## Gender

Male

## Phase

2

## Groups that have been masked

No information

## Sample size

Target sample size: **146**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

Randomization: random assignment of the patients to the intervention and control groups using balance block randomization of 4 groups. Blinding: patients will be under the local anesthesia and will not aware of the type of intervention. Therefore, the trial will be run as single blind.

## 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

2014-05-17, 1393/02/27

#### Ethics committee reference number

D/P/16/35/9/710

## Health conditions studied

### 1

#### Description of health condition studied

Varicocele

#### ICD-10 code

I86.1

#### ICD-10 code description

Varicocele

## Primary outcomes

### 1

#### Description

measuring the pain severity

#### Timepoint

one week, one month, and three months after surgery

#### Method of measurement

using VAS scale

## Secondary outcomes

### 1

#### Description

Nothing

#### Timepoint

Nothing

#### Method of measurement

Nothing

## Intervention groups

### 1

#### Description

Varicolectomy with inguinal herniorrhaphy

#### Category

Treatment - Surgery

### 2

#### Description

Varicolectomy without inguinal herniorrhaphy

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Beheshti Hospital

##### Full name of responsible person

Dr Ehsan Ghaneei

##### Street address

Shahid Beheshti Hospital, Eram 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**

Shahid Beheshti Hospital

**Full name of responsible person**

Dr Ehsan Ghaneei

**Position**

Medical student

**Other areas of specialty/work**

**Street address**

Shahid Beheshti Hospital, Eram Ave.

**City**

Hamadan

**Postal code**

**Phone**

+98 81 3838 0283

**Fax**

**Email**

e\_ghaneei@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Shahid Beheshti Hospital

**Full name of responsible person**

Dr Sasan Mehrabi

**Position**

Pediatric Urologist

**Other areas of specialty/work**

**Street address**

Shahid Beheshti Hospital, Eram Ave.

**City**

Hamadan

**Postal code**

**Phone**

+98 81 3838 0283

**Fax**

**Email**

mehrabi.sasan@yahoo.com

**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Department of Epidemiology & Biostatistics

**Full name of responsible person**

Dr Jalal Poorolajal

**Position**

Associate Professor of Epidemiology

**Other areas of specialty/work**

**Street address**

School of Public Health, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

**City**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0090

**Fax**

**Email**

poorolajal@umsha.ac.ir

**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*