

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Effect of varicocelelectomy with or without inguinal herniorrhaphy on Scrotum pain in patients with varicocele

Protocol summary

Study aim

Determining the effect of varicocelelectomy with and without inguinal herniorrhaphy on the severity of scrotum pain in patients with varicocele.

Design

A clinical trial with a control group, with parallel groups, double-blind, phase 3 will be conducted on 146 patients. Rand function of Excel software will be used for randomization.

Settings and conduct

This study will be conducted on patients with painful varicocele in Shahid Beheshti Hospital in Hamadan. In this study, eligible patients will be randomly assigned to two groups. In one group of patients, varicocelelectomy surgery will be performed with inguinal herniorrhaphy and in the other group, varicocelelectomy surgery will be performed without inguinal herniorrhaphy. The study will be conducted in a double-blind manner. Patients and the person who evaluates the outcome of pain after surgery will be unaware of performing or not performing inguinal herniorrhaphy during varicocelelectomy

Participants/Inclusion and exclusion criteria

The participants in the study are patients aged 18 to 65 years with varicocele accompanied by pain. Patients who have painless varicocele or have surgical contraindications for varicocelelectomy or herniorrhaphy will not be included in the study.

Intervention groups

In one group of patients, varicocelelectomy will be performed with inguinal herniorrhaphy. In the other group, varicocelelectomy surgery will be performed without inguinal herniorrhaphy.

Main outcome variables

The main result of this study is the varicocele pain severity in the first week, first month and third month after surgery compared to before surgery, which is evaluated by the visual analogue scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151123025202N26**

Registration date: **2022-12-29, 1401/10/08**

Registration timing: **prospective**

Last update: **2022-12-29, 1401/10/08**

Update count: **0**

Registration date

2022-12-29, 1401/10/08

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2024-01-21, 1402/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of varicocele with or without inguinal herniorrhaphy on Scrotum pain in patients with varicocele

Public title

The effect of inguinal herniorrhaphy on scrotal pain after varicocele

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having varicocele Having symptoms of Scrotum pain

Exclusion criteria:

Having varicocele without pain Having contraindications for varicocele or herniorrhaphy

Age

From **18 years** old to **65 years** old

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **146**

Randomization (investigator's opinion)

Randomized

Randomization description

We made 146 cards and write letter I on 73 for intervention and on the other 73 letter C for the Control group. Then put them inside the envelope with aluminum wrap and put in a box. At the time of patient arrival, one of the envelopes randomly will be selected and open it, based on selected letter (I or C) patients will be assigned to intervention (varicocele with inguinal herniorrhaphy) or control (varicocele without inguinal herniorrhaphy) group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Due to the fact that the patient is under spinal anesthesia during the operation, he will not notice the type of intervention. Also, the person who evaluates the outcome of scrotal pain will be unaware of whether or not inguinal herniorrhaphy was performed during varicocele, so the study will be double blinded .

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamadan University of Medical Science

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Ethics committee of Hamadan University of Medical Science, shahid fahmideh Ave, Hamadan. Iran

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Approval date

2022-05-07, 1401/02/17

Ethics committee reference number

IR.UMSHA.REC.1401.133

Health conditions studied

1

Description of health condition studied

varicocele

ICD-10 code

B01.9

ICD-10 code description

Varicella without complication

Primary outcomes

1

Description

Scrotum pain intensity changes

Timepoint

Before surgery, one week, one month and three months after surgery

Method of measurement

With Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Performing varicocele surgery with inguinal herniorrhaphy

Category

Treatment - Surgery

2

Description

Intervention group: Performing varicocele surgery without inguinal herniorrhaphy

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Beheshti hospital

Full name of responsible person

Dr Sasan Mehrabi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Web page address**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Hamedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Coach

Latest degree

Master

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available