

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparative study of outcomes of laser hemorrhoidoplasty and conventional hemorrhoidectomy in patients with grade II-III hemorrhoids: a randomized clinical trial

Protocol summary

Study aim

Examining and comparing the intraoperative and postoperative results of two types of hemorrhoidectomy surgery (conventional hemorrhoidectomy and laser hemorrhoidoplasty)

Design

Randomized, parallel-group, unblinded clinical trial on 80 patients

Settings and conduct

All patients with hemorrhoids referred to Valiasr Hospital in Qom are randomly assigned to one of the intervention groups: conventional hemorrhoidectomy or laser hemorrhoidoplasty.

Participants/Inclusion and exclusion criteria

All patients over 18 years of age with hemorrhoids were included, and patients with a history of previous anal surgery were excluded.

Intervention groups

In laser hemorrhoidectomy surgery, a 2-3 mm skin incision is made at the anal edge of each pile and the laser fiber is inserted through the incision to the root of the internal hemorrhoid above the dentate line and is positioned in accordance with the laser fiber guide light. The laser device energy is set equal for each subgroup. The duration of each pulse for each group will be 3 seconds. This process is also performed for all other visible hemorrhoids of the patient. In the traditional surgical group that undergoes open hemorrhoidectomy (Milligan-Morgan). The hemorrhoid is grasped using Alice forceps or a hemostat and its removal from the internal anal sphincter is performed using monopolar diathermy until it reaches the base. Then the hemorrhoid base will be ligated and coagulated and a dressing will be applied. In the traditional surgical group, who undergo closed hemorrhoidectomy (Ferguson). The hemorrhoids are removed from the anorectal junction with a cautery, the base of the hemorrhoid base is transfixed, and the

surgical site is closed with sutures.

Main outcome variables

Intraoperative and Postoperative Pain and Bleeding

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250908067174N3**

Registration date: **2025-10-06, 1404/07/14**

Registration timing: **prospective**

Last update: **2025-10-06, 1404/07/14**

Update count: **0**

Registration date

2025-10-06, 1404/07/14

Registrant information

Name

Fateme Samiee

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 25 3660 9918

Email address

fateme1380samiee@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-10-23, 1404/08/01

Expected recruitment end date

2026-03-21, 1405/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of outcomes of laser hemorrhoidoplasty and conventional hemorrhoidectomy in patients with grade II-III hemorrhoids: a randomized clinical trial

Public title

Investigation of the results of laser and conventional hemorrhoid surgery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients over 18 years of age Patients with grade 2 and 3 hemorrhoids according to the Golliger classification who have not responded to medical treatments

Exclusion criteria:

Patients with grade four hemorrhoids Pregnant women Women who are menstruating at the time of surgery Patients with other anal diseases, including anal fistulas and abscesses, rectal cancers, and inflammatory bowel diseases that affect the rectum (Crohn's disease and ulcerative colitis) Thrombosed hemorrhoids Patients with recurrent hemorrhoids

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

To allocate patients to treatment groups (A: conventional hemorrhoidectomy and B: laser hemorrhoidopexy), a block randomization method with a fixed block size of 4 will be used. This approach is adopted to ensure appropriate balance and predictability of allocation throughout the study; in each block of four, two patients are always assigned to group A and two patients to group B. The exact allocation sequence in each block (such as AABB or BABA) will be selected completely randomly from six possible possibilities, and this sequence generation process will be performed by a statistician independent of the study implementation team. To ensure allocation concealment and prevent bias, the randomly generated sequences will be placed inside opaque, sealed, and numbered envelopes. The opaqueness of the envelopes ensures that the internal content (letter A or B) is not visible from the outside, and their sealing prevents premature opening. The final group assignment process takes place in the operating

room, just after the patient is put under anesthesia. At this point, the surgical team opens the next sealed envelope, and the letter inside the envelope determines the type of surgical intervention (A or B).

Blinding (investigator's opinion)

Not blinded

Blinding description**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 Sciences

Street address

5th Floor, Central Headquarters of University of Medical Sciences, Research Square, Shahid Fahmideh Blvd, Hamadan

City

Hamadan

Province

Hamadan

Postal code

۶۵۱۷۸۳۸۷۳۶

Approval date

2025-09-06, 1404/06/15

Ethics committee reference number

IR.UMSHA.REC.1404.444

Health conditions studied**1****Description of health condition studied**

Hemorrhoids

ICD-10 code

K64

ICD-10 code description

Hemorrhoids and perianal venous thrombosis

Primary outcomes**1****Description**

Post operative pain

Timepoint

24 hours, 3 days, 7 days, 14 days, and 1 month after surgery

Method of measurement

Visual analog scale

Secondary outcomes

1

Description

Symptoms of hemorrhoids (pain, bleeding, itching, dirt, and prolapse)

Timepoint

Before surgery and two weeks, one month, three months, six months after surgery

Method of measurement

Rorvik scale

Intervention groups

1

Description

Intervention group: Laser hemorrhoid surgery in lithotomy position with general anesthesia.

Category

Treatment - Surgery

2

Description

Intervention group: Hemorrhoid surgery performed using the conventional method (Milligan-Morgan-Ferguson) in the lithotomy position under general anesthesia.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital

Full name of responsible person

Rohollah Taghavi

Street address

Valiasr hospital., Jomhuri Blvd, Qom

City

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Ghoum

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Alireza Soltanian

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5th floor, Central Headquarters of University of Medical Sciences, Shahid Fahmideh Blvd., Hamadan, Hamedan

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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

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

Hamedan University of Medical Sciences

Full name of responsible person

Rohollah Taghavi

Position

Non-faculty specialist physician

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Title and more details about the data/document

The information of all the participants without individual information will be published in most of the tables as a general conclusion.

When the data will become available and for how long

After the end of the patient admission and the final analysis of the data

To whom data/document is available

The general public

Under which criteria data/document could be used

In order to increase people's awareness in the field of hemorrhoid surgery methods and to improve the clinical skills of patients in the field of choosing a more effective surgical method according to the lifestyle and clinical condition of patients.

From where data/document is obtainable

Valid databases for publishing articles

What processes are involved for a request to access data/document

Refer to the desired database and use keywords to access the article

Comments

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Fateme Samiee

Position

Master's student

Latest degree

Bachelor

Other areas of specialty/work

Operating room

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