Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Iran (Islamic Republic of)

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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
۶۵۱۷۸۴۷۳۶
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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
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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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Person responsible for scientific inquiries

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Position
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Latest degree
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Person responsible for updating data

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Position
Master's student

Latest degree
Bachelor

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Operating room

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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