

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

A Comparative Study between the Therapeutic Results of Laser Hemorrhoidoplasty and Milligan-Morgan's Open Surgical Hemorrhoidectomy in Patients with Hemorrhoids

Protocol summary

Study aim

Investigating and comparing the therapeutic result and possible side effects in the treatment of grade 3 and 4 hemorrhoids according to the two methods of laser hemorrhoidectomy and Milligan Morgan surgery.

Design

clinical trial with control group, with parallel groups, non-blinded, randomized on 100 patients. Calculator round function is used for randomization.

Settings and conduct

after selecting, patients will be under general anesthesia then one group of patients underwent a Milligan Morgan hemorrhoidectomy surgery and other group underwent laser hemorrhoidoplasty treatment.

Participants/Inclusion and exclusion criteria

inclusion criteria: Ages over 18; grade III, IV hemorrhoids; non-respondent to medical treatment; willing to participate in the study; exclusion criteria: patients with Fissure; patients with Fistula; patients with Coagulation disorder; substance abuse; patients with Irritable bowel disease; patients who had hemorrhoid surgery treatment earlier

Intervention groups

In the control group, the procedure will be done as a Milligan Morgan classic method. in the intervention group, a 23 mm Proctoscope will be inserted into the anal canal . Once found, a 600micron optical fiber will subcutaneously be inserted into hemorrhoid through a 1 mm opening created with electrocautery in the anal vein (near the hemorrhoid base). Through optical fiber, then the laser device will be inserted into hemorrhoid and the coagulation occurs. Each shot has a power of 13 watts and a duration of 1.2 seconds. For each vessel, 5 shots will be fired 0.6 seconds apart. The other vessels will then be coagulated in a clockwise manner. The patient will be discharged 6-24 hours after surgery, depending on their physical condition.

Main outcome variables

Pain (0-10 VAS Score); Itching; Bleeding; Complications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200909048672N2**

Registration date: **2023-01-03, 1401/10/13**

Registration timing: **registered_while_recruiting**

Last update: **2023-01-03, 1401/10/13**

Update count: **0**

Registration date

2023-01-03, 1401/10/13

Registrant information

Name

Reza Eshraghi samani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2023-09-23, 1402/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
A Comparative Study between the Therapeutic Results of Laser Hemorrhoidoplasty and Milligan-Morgan's Open Surgical Hemorrhoidectomy in Patients with Hemorrhoids

Public title
evaluation of the therapeutic effect of hemorrhoidoplasty laser in hemorrhoids

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
aged > 18 years grade III, IV hemorrhoids non-respondent to medical treatment willing to participate in the study
Exclusion criteria:
patients with Fissure patients with Fistula patients with Coagulation disorder substance abuse Irritable bowel disease patients who had hemorrhoid surgery treatment earlier

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
First, in the form of consecutive sampling, before the operation the patients go to the surgical clinic one by one, and then the surgeon checks the inclusion and exclusion criteria, and if it was appropriate, he randomly places patients in group A or B, so that, The first person takes the last digit on the right side using the random function of calculator, and if the number is even, the person enters group A, and if the number is odd, he enters group B, and the second person is the opposite.

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
Research Ethics Committees of School of Medicine - Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Science- Hezar jirib Street- Isfahan
City
Isfahan
Province
Isfahan
Postal code
81746-73461
Approval date
2021-09-21, 1400/06/30
Ethics committee reference number
IR.MUI.MED.REC.1400.500

Health conditions studied

1

Description of health condition studied
Anal Hemorrhoid Grade III
ICD-10 code
K64.2
ICD-10 code description
Third degree hemorrhoids

2

Description of health condition studied
Anal Hemorrhoid Grade IV
ICD-10 code
K64.3
ICD-10 code description
Fourth degree hemorrhoids

Primary outcomes

1

Description
Pain
Timepoint
Before intervention and 1st, 4th and 12th weeks after intervention
Method of measurement
Visual Analogue Scale questionnaire

2

Description
Itching
Timepoint
Before intervention and 1st, 4th and 12th weeks after intervention
Method of measurement
asking the questions from patients

3

Description

Bleeding

Timepoint

Before intervention and 1st, 4th and 12th weeks after intervention

Method of measurement

asking the questions from patients

4

Description

Complications

Timepoint

1st, 4th and 12th weeks after intervention

Method of measurement

Visit by attending physician and asking the questions from patients

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Hemorrhoidectomy in Milligan Morgan procedure

Category

Treatment - Surgery

2

Description

Intervention group: Laser Hemorrhoidoplasty. To perform the procedure in the intervention group, a 23 mm Proctoscope will be inserted into the anal canal and a Doppler probe will search to find the upper rectal artery located 3 cm above the dentate line. Once found, a 600micron optical fiber will subcutaneously be inserted into hemorrhoid through a 1 mm opening created with electrocautery in the anal vein (near the hemorrhoid base). Through optical fiber, then the laser device will be inserted into hemorrhoid and the coagulation occurs. Each shot has a power of 13 watts and a duration of 1.2 seconds. For each vessel, 5 shots will be fired 0.6 seconds apart. The other vessels will then be coagulated in a clockwise manner. The patient will be discharged 6-24 hours after surgery, depending on their physical condition.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center**Name of recruitment center**

Alzahra Hospital

Full name of responsible person

Reza Eshraghi

Street address

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Web page address

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2

Recruitment center**Name of recruitment center**

Milad Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Askari

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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Reza Eshraghi
Position
Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All the data obtained from the study, including the data of the patients and statistical analysis maps and the results obtained after the official request from the competent authorities, will be provided to them.

When the data will become available and for how long

From the time of publication of the article for an unlimited period

To whom data/document is available

Official requests are answered from academic authorities and accredited scientific institutions and approved industrial centers.

Under which criteria data/document could be used

The data can be used to advance science in future articles or books, as well as to improve treatment methods with the help of new tools.

From where data/document is obtainable

Dr Reza Eshraghi eshraghireza@med.mui.ac.ir

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

Data will be announced after the approval of the main author of the article and the approval of the Research and Development Vice-Chancellor of Isfahan University of Medical Sciences

Comments