# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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 hemerroidoplasty 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**
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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 hemorrhidoplasty laser in hemorrhides

**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 Since- Hezar jirib Street- Isfahan

**City**

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**Province**

Isfehan

**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**
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## Sponsors / Funding sources

**1**

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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
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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**