# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

## A prospective randomized study of laser hemorrhoplasty (LHP) versus milligan and morgan hemorrhoidectomy In patients with hemorrhoids

## Protocol summary

**Study aim**
A prospective randomized study to compare laser hemorrhoplasty(LHP) and Milligan and Morgan hemorrhoidectomy In patients with hemorrhoids

**Design**
Phase 3, two arm parallel group, open label trial. 80 patients, enrolled between March 2011 and March 2013 followed for 6 months.

**Settings and conduct**
This study is carried on Ghaem and Sina Hospital in Mashhad, Iran. This study is an open label trial..

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: All patients are selected with two and three hemorrhoids Exclusion criteria: Patients who refused to collaborate and follow-up are excluded.

**Intervention groups**
In Intervention group surgery is done using laser and by LHP technique and in control group, surgery is done using Milligan and Morgan method.

**Main outcome variables**
Delayed bleeding; the presence of urinary retention; painful defecation; fistula; acute infection fissure; anal stenosis; fecal incontinence and postoperative thrombosis

## General information

**Reason for update**

**Acronym**
LHP

**IRCT registration information**
IRCT registration number: **IRCT20180204038605N1**
Registration date: **2018-04-01, 1397/01/12**
Registration timing: **retrospective**

Last update: **2018-04-01, 1397/01/12**
Update count: **0**

**Registration date**
2018-04-01, 1397/01/12

**Registrant information**

**Name**
Hosein Shabahang

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 51 3801 2840

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2012-07-21, 1391/04/31

**Expected recruitment end date**
2014-09-23, 1393/07/01

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
A prospective randomized study of laser hemorrhoplasty (LHP) versus milligan and morgan hemorrhoidectomy In patients with hemorrhoids

**Public title**
Study of Laser in the Treatment of Hemorrhoid Disease

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
All patients with hemorrhoid grade 2 or 3

**Exclusion criteria:**
Patients who refused to collaborate in follow-up

**Age**
No age limit
**Gender**
Both

**Phase**
3
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **80**
**Randomization (investigator's opinion)**
Not randomized
**Randomization description**
**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 Mashhad University of Medical Sciences
**Street address**
Ghaem Haspital, Ahmad abad street
**City**
Mashhad
**Province**
Razavi Khorasan
**Postal code**
9177899191
**Approval date**
2012-07-21, 1391/04/31
**Ethics committee reference number**
IR.MUMS.REC.1391.93

## Health conditions studied

### 1

**Description of health condition studied**
Digestive diseases
**ICD-10 code**
K90-K93
**ICD-10 code description**
K90-K93:Other diseases of the digestive system

## Primary outcomes

### 1

**Description**
Pain
**Timepoint**
Twenty-first day
**Method of measurement**
Visual Analogue Scale

## Secondary outcomes

### 1

**Description**
Quality of life Score
**Timepoint**
7 days
**Method of measurement**
SF-12 short questionnaire (12 questions)

## Intervention groups

### 1

**Description**
In Intervention group , surgery is done using laser and by LHP technique. Diod Lesar 1470 (Biolitec company) (CERALAS model) is used.The patients put under general anesthesia. After Prep and Drep, special optical fiber enter the hemorrhoidal packe. Then, the hemorrhoidal packe is measured from the proximal part to the distal part using LHP technique. In the next step, with a cotton 3.0 string, mucosopexy is performed from the proximal part to the distal part of the packe. At the end of the procedure, two or three packes are treated at a time.
**Category**
Treatment - Surgery

### 2

**Description**
In control group, surgery is done using Milligan and Morgan method. After Prep and Drep, the patients are under either general or spinal anesthesia. Afterwards, they are placed in the Lithotomy position. By this method, three hemorrhoid packes with at an angle of about 60° are selected. Then, the packe have to be eliminated below the tooth line of the anus while the skin and the mucous bridges between packes stayed preserved.
**Category**
Treatment - Surgery

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Ghaem Haspital, Mashhad University of Medical Sciences
**Full name of responsible person**

Hossein Shabahang
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Ghaem Haspital، Ahmad Abad Street
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Mashhad University of Medical Sciences
**Full name of responsible person**
University Research Deputy
**Street address**
Ahmad Abad Street
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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**
Mashhad 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**
Mashhad University of Medical Sciences
**Full name of responsible person**
Hossein Shabahang
**Position**
Associate professor
**Latest degree**
Specialist
**Other areas of specialty/work**
General Surgery
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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**
Not applicable
**Informed Consent Form**
Undecided - It is not yet known if there will be a plan to make this available
**Clinical Study Report**
Not applicable
**Analytic Code**
Not applicable
**Data Dictionary**
Not applicable