

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

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

#### Protocol summary

2018-04-01, 1397/01/12

#### 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

#### Registrant information

##### Name

Hosein Shabahang

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3801 2840

##### Email address

shabahang@mums.ac.ir

#### 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 Hospital, 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 Hospital, Mashhad University of Medical Sciences

##### Full name of responsible person

Hossein Shabahang  
**Street address**  
Ghaem Hospital, Ahmad Abad Street  
**City**  
Mashhad  
**Province**  
Razavi Khorasan  
**Postal code**  
9177899191  
**Phone**  
+98 51 3801 2806  
**Fax**  
+98 51 3843 6199  
**Email**  
shabahang@mums.ac.ir

## 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  
**City**  
Mashhad  
**Province**  
Razavi Khorasan  
**Postal code**  
9177899191  
**Phone**  
+98 51 3801 2806  
**Email**  
shabahang@mums.ac.ir  
**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  
**Street address**  
Ahmad Abad Street  
**City**  
Mashhad  
**Province**  
Razavi Khorasan  
**Postal code**  
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**Phone**  
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**Email**  
shabahang@mums.ac.ir

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Hossein Shabahang  
**Position**  
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Shabahang@mums.ac.ir

## Person responsible for updating data

#### Contact

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**Email**

Shabahangh@mums.ac.ir

**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