

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

shabahangh@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
shabahangh@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
shabahangh@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
9177899191
Phone
+98 51 3801 2806
Email
shabahangh@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
Associate professor
Latest degree
Specialist
Other areas of specialty/work
General Surgery
Street address
Ahmad Abad Street
City
Mashhad
Province
Razavi Khorasan
Postal code
9177899191
Phone
+98 51 3801 2806
Email
Shabahangh@mums.ac.ir

Person responsible for updating data

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
9177899191
Phone
+98 51 3801 2806
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