

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Comparison of intrahemorrhoidal coagulation using 980 nanometer diode LASER with Milligan Morgan hemorrhoidectomy in Shariati hospital in 2010-2012

Protocol summary

Summary

The purpose of the study is to compare efficacy and complication of "intrahemorrhoidal coagulation with 980 nanometer diode LASER" with "hemorrhoid resection using Milligan Morgan method". In this randomized controlled trial, 60 patients would be enrolled after taking informed consent. The patients are those with symptomatic hemorrhoids who have not responded to medical treatment. Those with extensive grade 4 lesions, drug-addicted patients and those with other simultaneous anorectal lesions (e.g. fissure) would be excluded. Patients would be randomly divided into two groups. One group undergo usual milligan Morgan hemorrhoidectomy and the other group are treated by intrahemorrhoidal coagulation with 980 nanometer diode LASER. Postoperative pain, narcotic use, complications and symptoms recovery (3 month later) would be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104272982N2**

Registration date: **2011-10-14, 1390/07/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-10-14, 1390/07/22

Registrant information

Name

Zhamak Khorgami

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 8490 2450

Email address

khorgami@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

As a thesis in Tehran University of Medical Sciences

Expected recruitment start date

2011-03-21, 1390/01/01

Expected recruitment end date

2012-03-20, 1391/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of intrahemorrhoidal coagulation using 980 nanometer diode LASER with Milligan Morgan hemorrhoidectomy in Shariati hospital in 2010-2012

Public title

Comparison of intrahemorrhoidal coagulation using 980 nanometer diode LASER with Milligan Morgan hemorrhoidectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: those with symptomatic hemorrhoids (mainly grade II and III) refractory to medical treatments
Exclusion Criteria: extensive circumferential grade 4 hemorrhoids, drug-addicted patients, other simultaneous anorectal problems (e.g. fissure)

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tehran University of Medical Sciences

Street address

Central building, Qhods avenue

City

Tehran

Postal code**Approval date**

2011-01-12, 1389/10/22

Ethics committee reference number

1275 / 130 / 89 / ۵

Health conditions studied**1****Description of health condition studied**

haemorrhoids

ICD-10 code

I84.9

ICD-10 code description

Unspecified haemorrhoids without complication

Primary outcomes**1****Description**

postoperative narcotic usage

Timepoint

continuous till time of discharge

Method of measurement

Patient controlled analgesia device

Secondary outcomes**1****Description**

postoperative urinary retention

Timepoint

At the time of discharge

Method of measurement

History taking

2**Description**

postoperative bleeding

Timepoint

At the time of discharge

Method of measurement

History taking and clinical records

3**Description**

operation time

Timepoint

At the end of surgery

Method of measurement

from start (after prep and drep) till end (before dressing)

4**Description**

Bleeding during surgery

Timepoint

At the end of surgery

Method of measurement

based on the number of wet gauzes

5**Description**

Postoperative pain

Timepoint

6 hour interval

Method of measurement

Visual analogue scale

6**Description**

Hospital stay

Timepoint

At the time of discharge

Method of measurement

based on medical reocords

7**Description**

Recovery of treated hemorrhoids

Timepoint

3 months after surgery

Method of measurement

Physical examination

8

Description

Surgical site infection

Timepoint

At the time of discharge and one week later

Method of measurement

Physical examination

9

Description

Recovery of symptoms

Timepoint

3 months after surgery

Method of measurement

History taking

Intervention groups

1

Description

control group: patients undergo general anesthesia with defined protocol and would be placed in lithotomy position. After anoscopy and determining abnormal hemorrhoidal pads, they are removed by elliptical incision from anal verge to anorectal ring. Then the base is suture ligated and wound is left open. Patient controlled analgesia device (PCAD)- contains 30 mg morphine sulfate in 30 cc normal saline - is connected in recovery unit and a loading dose is injected. Bolus volume and lock out time would be 1 cc (1 mg morphine) and 8 minutes respectively. Patient are educated before the procedure on how to work with PCAD. One dose of intravenous ceftriaxone and metronidazole given before and continues till 24 hours after surgery.

Category

Treatment - Surgery

2

Description

intervention group: patients undergo general anesthesia with defined protocol and would be placed in lithotomy position. After anoscopy and determining abnormal hemorrhoidal pads, each one would be coagulated using 980 nanometer diode LASER with 15 watts energy and 3 seconds pulses fired in parallel lines, 5 mm apart. No resection is done. Patient controlled analgesia device (PCAD)- contains 30 mg morphine sulfate in 30 cc normal saline - is connected in recovery unit and a loading dose is injected. Bolus volume and lock out time would be 1 cc (1 mg morphine) and 8 minutes respectively. Patient are educated before the procedure on how to work with PCAD. One dose of intravenous ceftriaxone and metronidazole given before and continues till 24 hours

after surgery.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

Zhamak Khorgami

Street address

Shariati Hospital, North Kargar Avenue,

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Shahin Akhonzade

Street address

Research deputy, Medicine faculty, Poursina avenue, Keshavarz Blvd

City

Tehran

Grant name

در قالب بودجه پایان نامه دستیار تخصصی

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences - Shariati Hospital

Full name of responsible person

Zhamak Khorgami

Position

General Surgeon / faculty of surgery department

Other areas of specialty/work**Street address**

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Tehran University of Medical Sciences - Shariati hospital

Full name of responsible person

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Position

General Surgeon / faculty of surgery department

Other areas of specialty/work**Street address**

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City**Person responsible for updating data****Contact****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty