# 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 symtoms 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)

**Phone**

+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 circumferencial 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 / د

## 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 eliptical 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**
Shariati Hospital, North Kargar Avenue
**City**
Tehran
**Postal code**
**Phone**
+98 21 8490 2450
**Fax**
+98 21 8863 3039
**Email**
khorgami@gmail.com
**Web page address**

## Person responsible for scientific 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**
Shariati Hospital, North Kargar Avenue
**City**
Tehran
**Postal code**
**Phone**
+98 21884902450
**Fax**
+98 21 8863 3039
**Email**
khorgami@gmail.com
**Web page address**

## 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*