Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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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
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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