

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of outcomes in open hemorrhoidectomy versus Ligasure hemorrhoidectomy

Protocol summary

Study aim

To compare outcomes in open hemorrhoidectomy versus ligasure hemorrhoidectomy.

Design

Randomized Controlled Trial

Settings and conduct

Department of Surgery, Allama Iqbal Teaching Hospital DG Khan.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients aged 25 – 65 years of either gender, planned to undergo surgery for grade III or IV hemorrhoids. Exclusion Criteria: Patients with recurrent hemorrhoids, rectal carcinoma (medical record) and patients with thrombosis of hemorrhoids (on clinical examination) will be excluded.

Intervention groups

This study has been planned to compare open versus ligasure hemorrhoidectomy (in terms of pain, bleeding, operative time, hospital stay, and urinary retention) in our local setting. Ligasure is considered safe procedure which does not need any special skill. However, Ligasure is an expensive device. Our study results will provide local evidence for surgeons to opt most beneficial surgical approach, keeping in view cost as well while dealing with patients having 3rd or 4th degree hemorrhoids. So, patients will get benefit of resuming their routine activities earlier and with ease.

Main outcome variables

Operative time: Time in minutes from induction of anesthesia to extubation of endotracheal tube. Time will be recorded by nursing staff using a stopwatch. Intra-operative blood loss: Amount of blood (in ml) collected in graduated bottles and pre- weighted surgical sponge (1-gram increase = 1 ml). Pain will be graded 24-hours postoperatively using visual analogue scale 0 – 10, where 0 is no pain and 10 is worst bearable pain.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250117064410N1**

Registration date: **2025-01-29, 1403/11/10**

Registration timing: **prospective**

Last update: **2025-01-29, 1403/11/10**

Update count: **0**

Registration date

2025-01-29, 1403/11/10

Registrant information

Name

waqas bhati

Name of organization / entity

Quetta Institute of Medical Sciences

Country

Pakistan

Phone

+92 81 2864601

Email address

tifal_bydagh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-02-01, 1403/11/13

Expected recruitment end date

2025-07-31, 1404/05/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of outcomes in open hemorrhoidectomy versus Ligasure hemorrhoidectomy

Public title

Comparison of open hemorrhoidectomy versus Ligasure hemorrhoidectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients aged 25 – 65 years of either gender, planned to undergo surgery for grade III or IV hemorrhoids.

Exclusion criteria:

Patients with recurrent hemorrhoids, rectal carcinoma (medical record) and patients with thrombosis of hemorrhoids (on clinical examination) will be excluded.

Age

From **25 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to group A and group B through lottery method using sealed opaque envelopes.

Blinding (investigator's opinion)

Single blinded

Blinding description

The patients will not know whether they are undergoing open or Ligasure hemorrhoidectomy.

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Review Committee, DG Khan Medical College
Dera Ghazi Khan

Street address

Jampur Road Dera Ghazi Khan

City

Dera Ghazi Khan

Postal code

32200

Approval date

2024-12-31, 1403/10/11

Ethics committee reference number

0011/198/MED/DGKMC

Health conditions studied

1

Description of health condition studied

hemorrhoids

ICD-10 code

K64

ICD-10 code description

Hemorrhoids and perianal venous thrombosis

Primary outcomes

1

Description

Operative time

Timepoint

From induction of anesthesia to extubation of endotracheal tube

Method of measurement

Time will be recorded by nursing staff using a stopwatch

2

Description

Intra-operative blood loss

Timepoint

Amount of blood (in ml) collected in graduated bottles and pre- weighted surgical sponge

Method of measurement

Amount of blood (in ml) collected in graduated bottles and pre- weighted surgical sponge (1-gram increase = 1 ml).

3

Description

Pain

Timepoint

It will be graded 24-hours postoperatively

Method of measurement

Using visual analogue scale 0 – 10, where 0 is no pain and 10 is worst bearable pain.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: A -open hemorrhoidectomy

Category

Treatment - Surgery

2

Description

Intervention group: B- Ligasure hemorrhoidectomy

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Allama Iqbal Teaching Hospital-DG khan medical college, Dera Ghazi Khan

Full name of responsible person

Dr Fatima Asad

Street address

Jampur Road Dera Ghazi Khan

City

Dera Ghazi Khan

Postal code

32200

Phone

+92 64 9260631

Email

info@dgkmc.edu.pk

Web page address

https://dgkmc.edu.pk/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

DG khan Medical College Dera ghazi khan

Full name of responsible person

Dr Fatima Asad

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

DG khan Medical College Dera ghazi khan

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

DG Khan Medical College

Full name of responsible person

Dr Fatima Asad

Position

Resident Surgeon

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

Street address

Derpartment of Surgery Allama Iqbal Teaching Hospital DG Khan

City

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Province

Punjab

Postal code

32200

Phone

N/A

Email

fatimaasad973@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

DG Khan Medical College

Full name of responsible person

Dr Fatima Asad

Position

Resident Surgeon

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All collected deidentified IPD

When the data will become available and for how long

after 31 July 2025, 6 months after publication

To whom data/document is available

For researches in the field of General Surgery

Under which criteria data/document could be used

After taking consent on email indicate clear purpose of the required information.

From where data/document is obtainable

From the Contact person (Dr Fatima Asad) through email

What processes are involved for a request to access data/document

Email to contact person indicating clear purpose for using the required information.

Comments