Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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@ymail.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
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+92 64 9260631
Email
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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
Street address
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Email
info@dgkmc.edu.pk
Web page address
https://dgkmc.edu.pk/
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
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Person responsible for scientific inquiries

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N/A

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Person responsible for updating data

Contact

Name of organization / entity
DG Khan Medical College

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Dr Fatima Asad

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Resident Surgeon

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Postal code
32200

Phone
N/A

Email
fatimaasad973@gmail.com

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 moths 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