

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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

**Street address**

Jampur Road Dera Ghazi Khan

**City**

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**Phone**

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**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**

Department of Surgery Allama Iqbal Teaching Hospital DG Khan

**City**

Dera Ghazi Khan

**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

**Street address**

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

DG Khan Medical College

**Full name of responsible person**

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**Position**

Resident Surgeon

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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Hospital DG Khan

**City**

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**Province**

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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 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**