

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparative outcomes of fistula LASER closure and open techniques in Fistula in Ano treatment

Protocol summary

Study aim

To compare the outcomes between Fistula LASER Closure and Fistulotomy/ Fistulectomy and Ligation of Inter-sphincteric Fistula Tract for the treatment of Fistula in Ano

Design

Pragmatic, community based, parallel group of 150 patients, not blinded, randomised controlled trial

Settings and conduct

Trial is not blinded. A total of 150 patients with primary anal fistula will be included. Group 1 will undergo FILAC and group 2 will undergo open procedure for treatment. Patients will be followed for a period of 3 months after the surgical procedure to compare outcomes between 2 groups. Each patient will be assessed for healing time, anal incontinence, recurrence and satisfaction level.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1. Patients who are ≥ 18 years and ≤ 60 years and are able to process the information and give informed consent 2. Patients reporting to General Surgical OPD with Primary Perianal Fistula, reporting first time with symptoms and confirmed through digital rectal examination. 3. Patients who are ASA I and ASA II
Exclusion Criteria: 1. Patients with anal incontinence 2. Patients with secondary causes of perianal fistula like tuberculosis, diabetes mellitus, inflammatory bowel disease, candidiasis and hidradenitis suppurativa 3. Patients who already underwent any perianal procedure

Intervention groups

A total of 150 patients will be included in the study as per sample size. Patients will be divided into 2 groups based on surgical procedure performed. Each group will contain 75 patients. Group 1 will undergo FILAC (LASER closure) and group 2 will undergo open procedure of fistulectomy/ fistulotomy/ Ligation of inter-sphincteric tract for perianal fistula treatment.

Main outcome variables

Outcomes will be determined by following variables: 1. Wound Healing Time 2. Anal Incontinence 3. Recurrence

4. Patient satisfaction level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260820070737N1**

Registration date: **2026-08-26, 1405/06/04**

Registration timing: **prospective**

Last update: **2026-08-26, 1405/06/04**

Update count: **0**

Registration date

2026-08-26, 1405/06/04

Registrant information

Name

Mahrukh Alam

Name of organization / entity

College of Physicians and Surgeons Pakistan

Country

Pakistan

Phone

+92 300 9189660

Email address

mahrukhalam_06@yahoo.com

Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2026-10-01, 1405/07/09

Expected recruitment end date

2027-04-01, 1406/01/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative outcomes of fistula LASER closure and open techniques in Fistula in Ano treatment

Public title

Fistula LASER closure in Fistula in Ano

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients reporting to General Surgical OPD with Primary Perianal Fistula, reporting first time with symptoms and confirmed through digital rectal examination Patients who are ASA I and ASA II Patients who are able to process the information and give informed consent

Exclusion criteria:

Patients with anal incontinence Patients with secondary causes of perianal fistula like tuberculosis, diabetes mellitus, inflammatory bowel disease, candidiasis and hidradenitis suppurativa Patients who already underwent any perianal procedure

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethical Committee/ Institutional review board of combined military hospital rawalpindi

Street address

Tamiz Ud Din Road, Rawalpindi

City

Rawalpindi

Postal code

46000

Approval date

2026-05-19, 1405/02/29

Ethics committee reference number

1026

Health conditions studied**1****Description of health condition studied**

Patients reporting to General Surgical OPD with Primary Perianal Fistula, reporting first time with symptoms and confirmed through digital rectal examination

ICD-10 code

K60.3

ICD-10 code description

Anal fistula

Primary outcomes**1****Description**

Recurrence

Timepoint

1 month after the intervention

Method of measurement

It will be assessed by occurrence of symptoms of perianal fistula after the symptom free period of at least one month once surgical treatment is given

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Group 1 will undergo FILAC

Category

Treatment - Surgery

2**Description**

Intervention group: Group 2 will undergo open procedure of fistulectomy/ fistulotomy/ Ligation of inter-sphincteric tract for perianal fistula treatment

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

General Surgery OPD of Combined Military Hospital

Rawalpindi
Full name of responsible person
Mahrukh Alam
Street address
Tamiz Ud Din Road Rawalpindi
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46000
Phone
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Email
mahrukhalam_06@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
PI initiated (personal)
Full name of responsible person
Mahrukh Alam
Street address
Tamiz Ud Din Road Rawalpindi
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Phone
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Email
mahrukhalam_06@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Combined Military Hospital Rawalpindi
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
Other

Person responsible for general inquiries

Contact

Name of organization / entity
College of Physicians and Surgeons Pakistan
Full name of responsible person
Mahrukh Alam
Position
Post Graduate
Latest degree

Medical doctor
Other areas of specialty/work
General Surgery
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Person responsible for updating data

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

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable