Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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
City
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Postal code
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mahrukhalam_06@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
PI initiated (personal)
Full name of responsible person
Mahrukh Alam
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Tamiz Ud Din Road Rawalpindi
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+92 300 9189660
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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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mahrukhalam_06@yahoo.com

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