

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 2026

### Comparison between treatment efficacy of glyceryl trinitrate and lateral sphincterotomy for chronic anal fissure

#### Protocol summary

##### Study aim

To compare the treatment efficacy of medical therapy using glyceryl trinitrate versus surgical lateral sphincterotomy in patients with chronic anal fissure

##### Design

Parallel group, double blinded randomized controlled trial

##### Settings and conduct

The study was carried out at CMH Peshawar, the population under study were patients with chronic anal fissure requiring treatment, since the procedural limitation did not allow patients blinding, the surgical specialists conducting the surgical procedure and the resident surgeon advising and applying the medical treatment (glyceryl trinitrate) were blinded to the study protocol using proformas marked X and Y for endorsing study outcomes in both groups respectively. The final analysis was carried out by an independent team unaware of the treatment modality given in patients and only outcomes variables were given to them for analysis

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: all patients more than 18 years of age; with a chronic non-healing anal fissure more than 8 weeks duration; presenting to the surgical out-patient department for treatment. Exclusion criteria: pregnancy, non-compliant to follow-up, history of recurrent anal fissures; surgical or medical intervention in the last 6 months; patients with major cardiac or respiratory disease; patients unwilling to be included in the study.

##### Intervention groups

Intervention Group 1: Group S (n=120) to receive surgical lateral sphincterotomy. Lateral sphincterotomy was done by dissecting part of the internal anal sphincter to relieve fissure induced spasm. Intervention Group 2: Group M (n=95) to receive glyceryl trinitrate. glyceryl trinitrate 0.2% (1-2ml) was used as local applicant not the fissure area to relieve spasm

##### Main outcome variables

Mean time for complete healing of the fissure, frequency of ulcer healing; median pain scores as assessed on the

NRS (numerical rating scale); frequency of bleeding

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20231201060234N1**

Registration date: **2024-06-22, 1403/04/02**

Registration timing: **retrospective**

Last update: **2024-06-22, 1403/04/02**

Update count: **0**

##### Registration date

2024-06-22, 1403/04/02

##### Registrant information

##### Name

Rashid Ali

##### Name of organization / entity

Bolan medical college quetta

##### Country

Pakistan

##### Phone

+92 81 2850639

##### Email address

rashid\_zahidbaloch@hotmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-01-01, 1401/10/11

##### Expected recruitment end date

2023-06-30, 1402/04/09

##### Actual recruitment start date

2023-01-01, 1401/10/11

##### Actual recruitment end date

2023-06-30, 1402/04/09

**Trial completion date**

empty

**Scientific title**

Comparison between treatment efficacy of glyceryl trinitrate and lateral sphincterotomy for chronic anal fissure

**Public title**

Medical versus surgical treatment for chronic anal fissure

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients more than 18 years of age With a chronic non-healing anal fissure more than 8 weeks duration Presenting to the surgical out-patient department for treatment.

**Exclusion criteria:**

Pregnancy Recurrent anal fissures Major cardiac or respiratory disease Unwilling to be included in the study

**Age**

From **18 years** old

**Gender**

Both

**Phase**

1-2

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **240**

Actual sample size reached: **240**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple randomization was done using individual type. The method used was chits marked X and Y using the lottery method. The sealed chits were selected once the patient entered the recovery room. The resident surgeon deputed for patient selection of the chits was unaware of the study protocol and allocation concealment was done. Only the consultant in the operating room was aware of the protocol.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Both the final assessor and data analyzer were unaware of the study protocol

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethical Review board CMH Peshawar

**Street address**

Mall road; Peshawar

**City**

Peshawar

**Postal code**

25000

**Approval date**

2023-02-07, 1401/11/18

**Ethics committee reference number**

CMH- PSC-0056

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

Chronic anal fissure

**ICD-10 code**

K60.1

**ICD-10 code description**

Chronic anal fissure

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

Mean time to complete fissure healing

**Timepoint**

Assessed weekly after intervention till endpoint of healing or failure of healing after 8 weeks

**Method of measurement**

Subjective assessment by a surgical consultant

**Secondary outcomes****1****Description**

Median pain scores

**Timepoint**

Weekly will 8 weeks

**Method of measurement**

Visual analog pain score by a surgical consultant

**2****Description**

Episodes of bleeding post-procedure

**Timepoint**

Weekly for 8 weeks after procedure

**Method of measurement**

Assessment subjectively by a consultant surgical specialist

## Intervention groups

### 1

#### Description

Intervention group 1: Surgical lateral sphincterotomy group. Patients in Group S received the surgical procedure by a consultant surgeon and part of the internal anal sphincter was dissected to relieve the fissure induced spasm and were followed up till 8 weeks at 4,6 and 8 week duration for the primary and secondary outcomes mentioned.

#### Category

Treatment - Surgery

### 2

#### Description

Intervention group 2: Glyceryl trinitrate group. Patients received 0.2% ointment of glyceryl trinitrate and directed by a resident surgeon on its correct application in the perianal area using 1-2 ml twice a day for a total of 8 weeks and followed up similarly at 4,6 and 8 weeks duration.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

CMH Peshawar

##### Full name of responsible person

Dr. Rashid

##### Street address

CMH Road

##### City

Peshawar

##### Postal code

25000

##### Phone

+92 333 3384051

##### Email

rashid\_zahidbaloch@hotmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

CMH Peshawar

##### Full name of responsible person

Dr Rashid Baloch

##### Street address

CMH Road

##### City

Peshawar

##### Postal code

25000

##### Phone

+92 333 3384051

##### Email

rashid\_zahidbaloch@hotmail.com

##### Grant name

None

##### Grant code / Reference number

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

Yes

##### Title of funding source

CMH Peshawar

##### 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

CMH Peshawar

##### Full name of responsible person

Rashid Ali

##### Position

PG Gen surgery

##### Latest degree

Medical doctor

##### Other areas of specialty/work

General Surgery

##### Street address

D7

##### City

Peshawar

##### Province

KPK

##### Postal code

25000

##### Phone

+92 81 2850639

##### Fax

##### Email

Rashid\_zahidbaloch@hotmail.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

CMH Peshawar

##### Full name of responsible person

Rashid Ali

##### Position

PG Gen surgery

##### Latest degree

Medical doctor  
**Other areas of specialty/work**  
General Surgery  
**Street address**  
D7  
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**Province**  
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Rashid\_zahidbaloch@hotmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
CMH Peshawar  
**Full name of responsible person**  
Rashid Ali  
**Position**  
PG Gen surgery  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
General Surgery  
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**Province**  
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**Postal code**  
25000  
**Phone**  
+92 81 2850639  
**Fax**  
**Email**

Rashid\_zahidbaloch@hotmail.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

Yes - There is 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 the data including patients records (excluding patient identification IDs), excel sheets, analysis proformas and SPSS output sheets will be made available to all researchers for academic purposes when requested through online repository, link of which will be shared once approval given from the primary author and the institute in which the study was carried out

### When the data will become available and for how long

Will be available indefinitely pending approval by the primary author and institute

### To whom data/document is available

For academic purposes only

### Under which criteria data/document could be used

The manuscript along with SPSS data sets and output sheets will be shared once published by the journal Will be shared via email

### From where data/document is obtainable

Will be sent both my email and will be available online and link would be provided as well on Google Drive

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

Email to the institute and the primary author

### Comments