Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

City

Peshawar

Province

KPK

Postal code

25000

Phone

+92 81 2850639

Fax

Email

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

Street address

D7

City

Peshawar

Province

KPK

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