

Unilateral versus bilateral internal sphincterotomy: a randomised controlled trial for chronic fissure-in-ano

Submission date 06/09/2007	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 24/09/2007	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 06/08/2021	Condition category Digestive System	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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India
560007

Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Unilateral versus bilateral internal sphincterotomy: a randomised controlled trial for chronic fissure-in-ano

Study objectives

Alternative or research hypothesis:

The established surgery has a recurrence rate and there is chance of anal incontinence. There is no surgery which can be considered ideal. This new surgical intervention is likely to give better results than the established procedure.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Medical Research Committee of the Armed Forces Medical College (AFMC), Pune, India on the 26th December 2003 (ref: 2248/AFMRC/EC).

Study design

Randomised, active controlled trial. Randomisation performed by sealed envelope method.

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Chronic fissure-in-ano

Interventions

Group A (active control): single internal lateral sphincterotomy

Group B: (new treatment): double internal lateral sphincterotomy

A minimum follow up of 6 months.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. Post-operative pain
2. Recurrences

Key secondary outcome(s)

1. Healing of fissure, measured at 3 to 6 months
2. Incontinence to flatus and faecal matter, measured from the date of surgery until 6 months in the form of use of pad, soiling of undergarment

Completion date

31/08/2006

Eligibility

Key inclusion criteria

1. Disease over one year
2. Aged more than 18 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

211

Key exclusion criteria

1. Oral medication with nitrates, calcium channel blocker
2. Past ano-rectal surgery
3. Elderly lady with old perineal tear

Date of first enrolment

01/01/2004

Date of final enrolment

31/08/2006

Locations**Countries of recruitment**

India

Study participating centre

PG Department of Surgery

Bangalore

India

560007

Sponsor information

Organisation

Command Hospital Air Force Bangalore (CHAFB) (India)

ROR

<https://ror.org/05cx69s52>

Funder(s)**Funder type**

Other

Funder Name

Investigator initiated and funded (India)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/01/2010	06/08/2021	Yes	No