

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

<b>Submission date</b> 06/09/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 24/09/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/08/2021	<b>Condition category</b> Digestive System	<input type="checkbox"/> 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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Bangalore  
India  
560007

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

## 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 measure**

1. Post-operative pain
2. Recurrences

**Secondary outcome measures**

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

**Overall study start date**

01/01/2004

**Completion date**

31/08/2006

**Eligibility****Key inclusion criteria**

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

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Over 100 on each arm, total more than 200

**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)

## Sponsor details

c/o Dr A.K. Pujahari

PG Department of Surgery

Air Force

Bangalore

India

560007

## Sponsor type

Hospital/treatment centre

## ROR

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

# Funder(s)

## Funder type

Other

## Funder Name

Investigator initiated and funded (India)

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## 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?
<a href="#">Results article</a>		01/01/2010	06/08/2021	Yes	No