ISRCTN60893979 https://doi.org/10.1186/ISRCTN60893979

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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 24/09/2007	**Overall study status** Completed	
Last Edited 06/08/2021	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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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 then 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 sphinterotomy
Group B: (new treatment): double internal lateral sphinterotomy

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
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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?
Results article		01/01/2010	06/08/2021	Yes	No