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

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Aswini Pujahari

Contact details
PG Department of Surgery
Command Hospital Air Force Bangalore (CHAFB)
Bangalore
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 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

Study type(s)
Treatment

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(s)
1. Post-operative pain
2. Recurrences

Key secondary outcome(s))
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

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