

Anal fistula plug versus endorectal advancement flap for the closure of high criptoglandular fistula-in-ano: a randomised study

Submission date 29/10/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/11/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 20/11/2008	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

A randomised study to compare the results of the anal fistula plug (AFP) with the endorectal advancement flap (ERAF) in the treatment of high fistula-in-ano of cryptoglandular origin

Study objectives

The use of lyophilised porcine submucosal plugs (Cook Surgisis®, AFPTM) has been proposed as an alternative to conventional surgical techniques for the treatment of anal fistulas. Rates of favourable outcomes are highly variable in the literature (between 13.9% and 87%).

Unfortunately, some reports are retrospective studies, others are prospective cohort studies, and only one study has compared the efficacy of this technique with a retrospective review of patients treated with endorectal advancement flap (ERAF). Additionally, these studies include simple and complex anal fistulas, anovaginal fistulas and patients with inflammatory bowel disease. So far, there is not a randomised study comparing the AFP with other surgical procedures suitable for high fistulas. Therefore, the objective of this randomised study was to compare the results of AFP with ERAF in the treatment of high fistula-in-ano of cryptoglandular origin.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Comité Ético de Investigación Clínica of the Health Department of the Government of Navarra (Spain) gave approval on the 2nd April 2007 (ref: Pyto. 14_07).

Study design

Interventional randomised single-centre trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Fistula-in-ano of cryptoglandular origin

Interventions

All patients underwent full mechanical bowel preparation and received antibiotic and antithromboembolic prophylaxis. The patients were operated on under general anaesthesia in the lithotomy position. Surgical procedures were performed by two surgeons with accredited degrees in Coloproctology (ESBQ Coloproctology).

Anal fistula plug (AFP):

The plug was submerged in saline for two minutes; the internal fistula orifice was located by injecting hydrogen peroxide. Curettage of the track was not performed. A probe was inserted in the fistula track. The AFP was placed into the tract until resistance was felt and then fixed in place with a 2-0 polyglactin suture (Vicryl®) which included the internal sphincter. The suture was tied in order to close the internal opening of the fistula over the plug. Care was taken to ensure that the external orifice of the fistula was not completely occluded in order to allow the track to drain. The remaining plug was cut at the level of the external opening.

Endorectal advancement flap:

The tract of the fistula was completely excised, including the internal opening. A rectal flap above the internal opening was mobilised, including the mucosa and submucosa, with a 3 to 4 cm broad base. The rectal flap was mobilised sufficiently to cover the internal opening.

Exhaustive haemostasis was performed to avoid a haematoma under the flap. Finally, the flap was sutured to the edge of the anal canal, covering the internal opening.

Average duration of treatment:

Anal Fistula Plug: 30 minutes

Endorectal Advancement Flap: 90 minutes

Total duration of follow-up for all arms of your trial: one year

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Fistula closure rate; recurrence is defined as the presence of an abscess arising in the area, or by obvious evidence of fistulation. Evaluated at 2, 4, 8, 12 weeks after surgery, and at 6, 9 and 12 months.

Key secondary outcome(s)

Continence, evaluated pre- and post-operatively (after one year) using the Wexner score.

Completion date

30/04/2009

Eligibility

Key inclusion criteria

1. Aged above 18 years, either sex
2. High fistula-in-ano of cryptoglandular origin (the fistulas were defined as high when they included the upper two-thirds of the external sphincter complex)
3. Informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Secondary tracts
2. Horseshoe fistulas
3. Anovaginal fistulas
4. Rectouretral fistulas
5. Human immunodeficiency virus (HIV)-positive patients
6. Diagnosed from Crohn's disease

Date of first enrolment

01/05/2007

Date of final enrolment

30/04/2009

Locations

Countries of recruitment

Spain

Study participating centre

C/Trinidad Fernandez Arenas

Pamplona

Spain

31002

Sponsor information

Organisation

Hospital Virgen del Camino (Spain) - Public University of Navarra

ROR

<https://ror.org/046wwwv897>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Hospital Virgen del Camino (Spain) - Public University of Navarra

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes