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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	[_] Prospectively registered [_] Protocol
Registration date 20/11/2008	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 20/11/2008	**Condition category** Digestive System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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.

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

Overall study start date
01/05/2007

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
186 patients (93 in each group)

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

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/046wwv897

Funder(s)

Funder type
Hospital/treatment centre

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

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