

The anal fistula PLUG versus the mucosal flap advancement for the treatment of perianal fistulas

Submission date 16/07/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 16/07/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 31/12/2020	Condition category Digestive System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
The anal fistula PLUG versus the mucosal flap advancement for the treatment of perianal fistulas

Acronym
PLUG

Study objectives

The anal fistula plug is superior in the treatment of high transphincteric fistulas compared to the mucosal advancement flap.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the Medical Ethics Committee AMC, Amsterdam on the 23rd August 2006 (ref: MEC 06/204).

Study design

Multicentre, randomised, double blinded, active controlled, parallel group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Perianal fistula

Interventions

installation of the anal fistula plug versus mucosal flap.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. Anorectal fistula closure rate
2. Continence

Key secondary outcome(s)

1. Morbidity
2. Post-operative pain
3. Sick leave
4. Quality of life

Completion date

01/10/2007

Eligibility**Key inclusion criteria**

1. High anorectal fistula of cryptoglandular origin (transphincteric, upper 2/3 of the sphincter complex which is confined by the puborectal sling and the end of the anal canal)
2. Informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

Total final enrolment

60

Key exclusion criteria

1. Aged less than 18 years
2. Human Immunodeficiency Virus (HIV)-positive
3. Crohn's disease
4. Malignant cause
5. Tuberculosis
6. Hidradenitis suppurativa
7. Pilonidal sinus disease
8. No internal opening found during surgery

Date of first enrolment

01/10/2006

Date of final enrolment

01/10/2007

Locations**Countries of recruitment**

Netherlands

Study participating centre

Academic Medical Centre

Amsterdam

Netherlands

1105 AZ

Sponsor information

Organisation

Academic Medical Centre (AMC) (The Netherlands)

ROR

<https://ror.org/03t4gr691>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Academic Medical Centre (AMC) (The Netherlands)

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	results	01/04/2011	31/12/2020	Yes	No
Protocol article	protocol	23/06/2008	31/12/2020	Yes	No