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

Submission date Recruitment status Prospectively registered 16/07/2007 No longer recruiting [X] Protocol Statistical analysis plan Overall study status Registration date 16/07/2007 Completed [X] Results [] Individual participant data Last Edited Condition category 31/12/2020 Digestive System

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

- 1. Anorectal fistula closure rate
- 2. Continence

Secondary outcome measures

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

Overall study start date

01/10/2006

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

Age group

Adult

Sex

Not Specified

Target number of participants

60

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)

Sponsor details

Department of Surgery P.O. Box 22660 Amsterdam Netherlands 1100 DD

Sponsor type

Hospital/treatment centre

Website

http://www.amc.uva.nl#http://www.amc.uva.nl/

ROR

https://ror.org/03t4gr691

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Academic Medical Centre (AMC) (The Netherlands)

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