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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	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 16/07/2007	**Overall study status** Completed	
Last Edited 31/12/2020	**Condition category** Digestive System	

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
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