

ABS; transvaginal vs peri-anal approach.

No registrations found.

Ethical review	Not applicable
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23692

Source

Nationaal Trial Register

Brief title

ABS

Health condition

Faecal incontinence.

Sponsors and support

Primary sponsor: University Hospital Maastricht

Source(s) of monetary or material Support: University Hospital Maastricht

Intervention

Outcome measures

Primary outcome

Infection.

Secondary outcome

1. Quality of life;

2. Incontinence scores.

Study description

Background summary

Randomised trial to compare infection rate in two surgical techniques to implant an Artificial Bowel Sphincter. We compare the peri-anal incision vs the transvaginal incision.

Study objective

Transvaginal implantation of ABS system reduces the risk of infection.

Study design

Preoperative quality of life and incontinence score assessment. 3 months after operation
postoperative quality of life and incontinence score assessment.

Infection in 6 weeks after surgery.

Intervention

1. Artificial bowel sphincter system;
2. implantation.

Contacts

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Eligibility criteria

Inclusion criteria

1. Females
2. Informed consent
3. Older than 18 years
4. On the waiting list for ABS implantation.

Exclusion criteria

1. Males
2. ABS revision
3. New ABS implantation after prior explantation due to infection.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Suspended
Start date (anticipated):	01-03-2008
Enrollment:	70
Type:	Anticipated

Ethics review

Not applicable	
Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1176
NTR-old	NTR1221
Other	:
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

All results will be published. No publications yet.