

Laparoscopic sacrocolpopexy using bone anchor fixation in cases of vaginal vault prolapse.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26956

Source

NTR

Health condition

prolapse
incontinence

Sponsors and support

Primary sponsor: Performer: Sint Franciscus Gasthuis, Rotterdam, The Netherlands.

Source(s) of monetary or material Support: No funding

Intervention

Outcome measures

Primary outcome

Succesfull reduction of prolaps:

1. Anatomically, classification with POP-Q system;
2. In terms of patient satisfaction with validated questionnaires (Urogenital Distress Inventory

(UDI), Incontinence Impact Questionnaire (IIQ) and the Defecatory Distress Inventory (DDI))¹¹.

Secondary outcome

Urodynamic parameters and lower urinary tract symptoms.

Study description

Background summary

Application of the laparoscopic bone anchor inserter in laparoscopic sacrocolpopexy is an easy and safe procedure that provides firm fixation and excellent anatomical results. The present observational study addresses long term results and patient satisfaction and includes sequential urodynamic assessment.

Study objective

N/A

Study design

1. A minimal follow up of 6 months;
2. Urodynamic evaluation scheduled 3-6 months after surgery.

Intervention

Laparoscopic sacrocolpopexy with use of titanium bone anchor and polypropylene mesh.

Contacts

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Eligibility criteria

Inclusion criteria

Patients with vaginal vault prolapse after a previous hysterectomy.

Exclusion criteria

1. Preceding rectosigmoid resection;
2. Extensive intraabdominal and/or pelvic adhesions.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	12-01-2005
Enrollment:	50

Type:

Actual

Ethics review

Positive opinion

Date:

11-04-2011

Application type:

First submission

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	NL2711
NTR-old	NTR2849
Other	TWOR Protocol : 20004/57
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

Van der Weiden RMF, Withagen MIJ, Bergkamp ABM, Mannaerts GHH. A new device for bone anchor fixation in laparoscopic sacrocolpopexy. The Franciscan laparoscopic bone anchor inserter. Surg Endosc 2005; 19: 594-597.