Laparoscopische Rectal Prolapse Surgery. A two armed randomized clinical trial to compare Laparoscopic Ventral Rectopexy with Laparoscopic Resection Rectopexy for rectal prolapse surgery

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The objective is to determine the best surgical strategy for internal and external full thickness rectum prolapse in terms of morbidity, mortality, constipation, fecal continence, recurrence rates and quality-of-life of the treated individuals.

Ethical review	Not approved
Status	Will not start
Health condition type	Gastrointestinal therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON33144

Source
ToetsingOnline

Brief title
Laparoscopic Rectal Prolapse Surgery (LaProS)-study

Condition

- Gastrointestinal therapeutic procedures

Synonym
rectal prolaps

Research involving

Human

Sponsors and support

Primary sponsor: Meander Medisch Centrum
Source(s) of monetary or material Support: nog niet bekend.

Intervention

Keyword: Laparoscopic, Rectum prolapse, Resection rectopexy, Ventral rectopexy

Outcome measures

Primary outcome

Primary endpoint is the post-operative morbidity, measured by the number of hospital re-admissions and surgical reintervention needed.

Secondary outcome

Secondary endpoints are the comparision of pre- and postoperative: quality-of-life, incontinence (Vaizey-score), constipation (Altomare score), recurrence (physical exam / defecogram) and urogenital functioning (questionnaire and micturition diary). Futhermore, length of hospital stay, mortality, total in-hospital costs and the rate of extra outpatient visits are compared.

Study description

Background summary

A Rectal prolapse (RP), or procidentia, is the descent of the upper rectum, and can be either internal or through the anus (external), in which an internal rectal prolapse seems to be the precursor of an external prolapse. RP*s occur predominantly (80-90%) in women, of wich most after the fifth decade. The most common symptoms are fecal incontinence and constipation. Operation is the only definite treatment, and two main catogories can be indentified: perianal procedures and abdominal procedures. Due to higher recurrence rates in perianal

procedures and better functional outcome in the abdominal procedures, this latter approach has the preference in patients with low co-morbidity. Nowadays, a laparoscopic approach has the preference above the laparotomic approach because of less operation related morbidity. Two frequently applied abdominal procedures are the laparoscopic ventral rectopexy (mainly in Europe) and laparoscopic resection rectopexy (mainly in the USA). As there are no randomised trials comparing these techniques and there are no guidelines for clinical practice concerning rectal prolapse this study is designed to determine the best surgical strategy.

Study objective

The objective is to determine the best surgical strategy for internal and external full thickness rectum prolapse in terms of morbidity, mortality, constipation, fecal continence, recurrence rates and quality-of-life of the treated individuals.

Study design

Multicenter randomised clinical trial with an initial follow-up of 2 years and long-term follow-up up to 10 years.

Intervention

Two standardized surgical intervention techniques are compared. The first is the laparoscopic resection rectopexy (Frykman-Goldberg procedure, LRR), in which the rectal prolapse is treated by a resection of the rectum combined with suture rectopexy fixation of the rectosigmoid at the sacrum. The second is laparoscopic ventral rectopexy (LVR) in which the rectum is mobilised ventrally and fixed with a mesh from the sacrum to the ventral rectum.

Study burden and risks

-The potential benefit of participation in this study for this specific group of patients is the determination of the best treating method for rectum prolapse.
-The close follow-up regarding objective and subjective outcome of treatment in the studied subjects is also likely to be beneficial, as wel as additional research, done at 6 months of follow-up. This additional research will monitor possible recurrences of the rectal prolapse early.
Burdens:
-For both groups, the general risks of surgery are attached to the operations. We expect the risk of severe morbidity in the LRR group to be higher, mainly due to the risk of anastomotic leakage, approximately 10% versus 1% in the LVR group.
-The filling out of the quality of life questionnaires. The filling out of

these surveys will take approximately 30 minutes of the patient*s time pre-operative, as well as 30 minutes after six months of follow-up.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

-Internal or external full thickness rectal prolapse

Exclusion criteria

-Under 18 years old
-No rectal prolapse but bal or mucosa prolapse

-Rectosigmoid tumor or extensive diverticulitis
-Former rectosigmoid resection or rectal/vaginal prolapse surgery

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	330
Type:	Anticipated

Ethics review

Not approved

Date:	19-01-2010
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
CCMO	NL29325.100.09