The LaProS study. An international study to determine the optimal surgical treatment for rectal prolapse.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25259

Source
NTR

Brief title
LaProS study

Health condition

Rectal prolapse (Full thickness, external)

Sponsors and support

Primary sponsor: Departmant of general surgery, Meander Medical Center, Amersfoort, The Netherlands.
Source(s) of monetary or material Support: Fund = initiator = sponsor.

Intervention

Outcome measures

Primary outcome

Improvement of Quality of life, objectified by the Gastro-intestinal Quality of life Index (GIQLI).

Secondary outcome

1. To evaluate the optimal surgical strategy for laparoscopic rectal prolapse surgery in terms of improving constipation and incontinence (questionnaire, validated scoring systems: Cleveland Clinic Incontinence Score and Cleveland Clinic Constipation Score);

2. To evaluate and compare post-operative morbidity measured by reoperations, reinterventions, re-admissions and serious adverse events;

3. To evaluate the best surgical technique for rectal prolapse in terms of anatomic recurrence of the prolapse, measured by defecogram in rest and during Valsava manouvre;

4. To evaluate the rate of rectal prolapse recurrence and complications (complaints, physical examination, additional research, re-operation and readmission);

5. To evaluate pelvic floor function pre- and postoperatively (questionnaire);

6. To evaluate urogenital functioning pre- and postoperatively (questionnaire and urinary diary);

7. To evaluate quality of life pre- and postoperatively (faecal incontinence, obstructed defecation, voiding and quality-of-life scoring systems);

8. To evaluate length of hospital stay, peri-operative and post-operative in-hospital mortality and morbidity;

9. To evaluate the rate of extra outpatient visits because of complaints.

Study description

Background summary

Background:

Rectal prolapse (RP) is the descent of the upper rectum and
is a common problem in the western world. Surgery is the only definite treatment and is preferably performed minimally invasive. High-level prospective studies on treatment strategies for RP currently are lacking and, thus, no consensus exist regarding the optimal treatment for
patients with RP. Furthermore, remarkable transatlantic differences exist, as in Europe, laparoscopic ventral rectopexy (LVR) is regarded the treatment of choice, while in the USA Laparoscopic Resection Rectopexy (LRR) remains the golden standard.

Objective:

To determine the optimal minimally invasive surgical
treatment for patients with RP.

Design:

International, prospective, comparative double cohort study. The first cohort will consist of 120 European patients with a RP and will be treated with LVR. Centres in The Netherlands, Belgium and the UK are enlisted for participation. The second cohort will consist of 120 American patients with a RP, treated with LRR. Several US centres are enlisted. Pre-operative work-up consists of radiological imaging and standardised questionnaires. Follow-up (FU) is set on two years. During FU, pre-operative imaging and questionnaires will be repeated.

Primary & secondary outcomes:

Primary endpoint will be improvement on the Gastro-Intestinal-Quality-of-Life-Index (GIQLI). Secondary endpoints will be generic Quality-of-Life, functional results, morbidity, mortality, recurrences and cost-effectiveness.

Time frame:

Study and inclusion start will be on January the 1st, 2011
and will take approximately 18-24 months. Therefore, total study duration will be 42-48 months.

Study objective

N/A

Study design

Follow-up will be performed on the following moments:

1. 3-6 months after operation;

2. 12 months after operation;

3. 24 months after operation.

Intervention

Cohort 1 (European Cohort): Laparoscopic Ventral Rectopexy;

Cohort 2 (US Cohort): Laparoscopic Resection Rectopexy.

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Eligibility criteria

Inclusion criteria

All patients with an external rectal prolapse and an indication for laparoscopic ventral rectopexy (for European centers) or laparoscopic resection rectopexy (for US centers).

Exclusion criteria

1. Under 18 years of age;

2. Former rectosigmoid resection;

3. Former rectal prolapse surgery;

4. Rectosigmoid tumor;

5. Severe mental retardation;

6. Pregnant women.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2011
Enrollment:	240
Type:	Anticipated

Ethics review

Positive opinion

Date:	11-02-2011
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	NL2615
NTR-old	NTR2743
Other	:
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A