Cost-effectiveness of biological mesh closure of the pelvic floor after rectal cancer surgery.

De kosten-effectiviteit van een biologische mat voor het sluiten van de bekkenbodem na operatie voor laag gelegen endeldarm kanker.

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26577

Source
Nationaal Trial Register

Brief title
BIOPEX-study

Health condition

Wound healing, Extralevator abdominoperineal resection, Biological mesh, Rectal cancer, Perineal hernia

extralevatoire abdominoperineale resectie, rectumcarcinoom, biologische mat, wondgenezing, perineale hernia

Sponsors and support

Primary sponsor: dr. P.J. Tanis, Surgeon, Academic Medical Center, University of Amsterdam, the Netherlands
Source(s) of monetary or material Support: Investigator initiated study.
Grant application ZonMw currently under review.
Financial support by LifeCell.

Intervention

Outcome measures

Primary outcome

Primary endpoint is the percentage of uncomplicated perineal wound healing defined as a Southampton wound score less than II at 30 days postoperatively.

Secondary outcome

1. Perineal wound healing according to the Southampton wound grading at 3, 6, 9 and 2 months postoperatively;

2. Incidence of persistent perineal or presacral sinuses, both clinically and by imaging (routine follow-up CT);

3. Need for re-intervention or re-admission related to pre-sacral abscess or other perineal wound problems;

4. Length of hospital stay;

5. Need for nursing home admission;

6. Need for home nursing wound care: Frequency per week and total period of time;

7. Use of wound care material and devices like vacuum assisted closure;

8. Incidence of symptomatic and asymptomatic perineal hernia at 3, 6, 9 and12 months of follow-up;

9. Quality of life (EQ-5D, EORTC-30);

10. Costs.

Study description

Background summary

Approximately 800 abdominoperineal resections (APR) are performed for rectal cancer each year in the Netherlands. The extralevator approach (eAPR) reduces the rate of positive margins and improve oncological outcome in distal rectal cancer.
However, wider excisions increase wound healing problems and development of perineal hernia. This has resulted in a
progressive increase of the use of musculocutaneous flaps and biological meshes associated with a substantial increase of costs, which is not supported by proper data.
The aim of this study is to determine the cost-effectiveness of pelvic floor reconstruction using a biological mesh after
standardized eAPR with neo-adjuvant (chemo)radiotherapy.

HYPOTHESIS:

It is hypothesized that the use of a biological mesh will improve primary perineal wound healing and prevent secondary perineal
hernia formation compared to primary closure of the perineum.

STUDY DESIGN:

This is a multicenter study in which patients undergoing an eAPR are randomized between standard care using primary closure
of the perineum and the experimental arm with assisted closure using a biological mesh.

STUDY POPULATION:

Patients with a clinical diagnosis of primary rectal cancer who are scheduled for eAPR after neo-adjuvant (chemo)radiotherapy.

INTERVENTION:

The intervention in the experimental arm consists of suturing an acellular biological mesh derived from porcine dermis in the
pelvic floor defect, followed by perineal closure similar to the control arm.

OUTCOME MEASURES:

The primary endpoint is the percentage of uncomplicated perineal wound healing (Souphampton wound score less than II on
day 30). Secondary endpoints are hospital stay, incidence of perineal hernia, quality of life, and costs.

SAMPLE SIZE CALCULATION/DATA ANALYSIS:

A total number of 104 patients (52 per group) is needed in order to be able to detect an absolute 25% improvement in perineal wound healing (from 60% to 85%).

COST-EFFECTIVENESS ANALYSIS/ BUDGET IMPACT ANALYSIS:

Costs per uncomplicated wound healing and the costs per quality adjusted life-year will be determined. The budget impact will
be determined by balancing the additional costs of a biological mesh against decreased costs related to in hospital and home nursing wound care and less treatment of perineal hernia.

TIME SCHEDULE:

Patient inclusion untill 22 months, followed by 12 month of follow-up and 2 month of data analysis and reporting.

Study objective

It is hypothesized that the use of a biological mesh will improve primary perineal wound healing and prevent secondary perineal hernia formation compared to primary closure of the perineum.

Study design

At 7 and 30 days, 3, 6, 9 and 12 months.

Intervention

The perineal phase of the APR will be performed according to the principles of an extralevator APR. Preferably, an omental plasty is positioned in the pelvic cavity following resection.

The intervention in the experimental arm consists of suturing an acellular biological mesh derived from porcine dermis in the pelvic floor defect (Strattice™, 6x10 cm). The mesh will be sutured at each side of the coccyx or distal sacrum with Prolene or PDS to the discretion of the surgeon. Laterally, the mesh is attached to the remainings of the levator complex and, anteriorly, to the transverse perineal muscle or posterior vaginal wall. A suction drain will be inserted and positioned on top of the mesh. The perineal subcutaneous fat and skin will be subsequently closed in layers similar to primary simple closure as performed in the standard arm.

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Eligibility criteria

Inclusion criteria

1. Primary rectal cancer scheduled for eAPR after neo-adjuvant (chemo)radiotherapy;

2. Age of 18 years or higher;

3. Life expectancy of more than 2 years;

4. Ability to return for all scheduled and required study visits;

5. Written informed consent for study participation.

Exclusion criteria

1. Previous pelvic irradiation for other cancers (i.e. prostate cancer);

2. Total exenteration or sacral resection above level S4/S5;

3. Sensitivity to porcine derived products or polysorbate;

4. Severe systemic diseases affecting wound healing (i.e. renal failure requiring dialysis, liver cirrhosis, immune compromised status like HIV);

5. Collagen disorders (i.e. Marfan);

6. Enrollment in trials with overlapping primary endpoint or otherwise expected influence on wound healing (i.e. biological therapy like antiangiogenic agents).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2013
Enrollment:	104
Type:	Actual

Ethics review

Not applicable
Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 45096
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3560
NTR-old	NTR3717
CCMO	NL42094.018.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON45096

Study results

Summary results
N/A