Feasibility of a subcutaneous gluteal transposition flap without donor site scar for perineal closure after extralevator abdominoperineal resection for rectal cancer

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The aim of this study is to determine feasibility of perineal reconstruction using a gluteal subcutaneous transposition flap (Luna flap) after eAPR for rectal cancer.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anal and rectal conditions NEC
Study type	Interventional

Summary

ID

NL-OMON45650

Source
ToetsingOnline

Brief title
BIOPEX II Pilot study

Condition

- Anal and rectal conditions NEC
- Gastrointestinal therapeutic procedures

Synonym
rectal cancer., Rectal malignancy

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Abdominoperineal resection, Rectum neoplasms, Wound healing

Outcome measures

Primary outcome

Primary endpoint is flap failure at 30 days postoperatively. Vascularization cannot be checked postoperatively in the absence of a skin island, because the flap is deepithelialized and the adjacent perineal skin is closed over the flap in the midline. Therefore, flap failure will be determined by its secondary impact on perineal wound healing. Flap necrosis will result in tissue breakdown, which is defined as a Southampton wound score of 5.

Secondary outcome

Secondary endpoints include uncomplicated perineal wound healing rate defined as a Southampton wound score of less than 2, and treatment related morbidity defined as Clavien-Dindo score of three or higher on day 30. Other outcome parameters include operative time needed for perineal closure, postoperative pain at 30 days postoperatively, hospital stay and perineal wound related re-intervention and re-admission.

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 improves oncological outcome in distal rectal cancer. However, wider excisions increase wound healing problems. 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. In addition the use of muscle flaps is associated with a risk of donor site morbidity.

Study objective

The aim of this study is to determine feasibility of perineal reconstruction using a gluteal subcutaneous transposition flap (Luna flap) after eAPR for rectal cancer.

Study design

This is a Pilot study in which patients undergoing an eAPR are treated with closure of the perineum using a Luna flap, after which the skin will be closed over the flap in the midline. The study will be conducted in two academic centers (AMC and Erasmus MC).

Intervention

The intervention consists of harvesting and stitching a subcutaneous transposition flap into the pelvic dead space, followed by perineal closure over the flap in the midline.

Study burden and risks

A potential additional risk related to the use of a Luna flap is flap failure, which may require a reoperation. However, this risk is considered to be low, based on our experience with fasciocutaneous gluteal transposition flaps in which the risk of flap necrosis is negligible.

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

(1) Rectal cancer (including recurrence). (2) Age of 18 years or higher. (3) Planned for extralevator abdominoperineal resection (4) Written informed consent for study participation.

Exclusion criteria

(1) Total exenteration or sacral resection above level S4/S5)
(2) Severe systemic diseases affecting wound healing
(3) The patient has a collagen diseases
(4) Participation of the patient in other scientific research affecting wound healing
(5) Non-correctable coagulopathy (INR>2; or platelets <90E9 109/l) present
(6) ASA-classification >= 4.

Study design

Design

Study phase:	2
Study type:	Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-03-2017
Enrollment:	11
Type:	Actual

Ethics review

Approved WMO Date:	26-10-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-05-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-12-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL58380.018.16