Multi-Interventional program for prevention and early Management of Anastomotic leakage after total mesorectal excision in Rectal cancer patlents, the IMARI-trial

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26456

Source
NTR

Brief title
IMARI-trial

Health condition

Anastomotic leakage after rectal cancer surgery

Sponsors and support

Primary sponsor: Prof. dr. P.J. Tanis, Surgeon, Academic Medical Center, University of Amsterdam, the Netherlands
Source(s) of monetary or material Support: KWF Dutch Cancer Society, Stryker, B. Braun

Intervention

Outcome measures

Primary outcome

The primary endpoint of the IMARI-trial is anastomotic integrity at one year postoperative.

Secondary outcome

The most important secondary aim is to determine the impact on the incidence of AL within 30 and 90 days and one year post-operation. Other outcomes include quality of life, protocol compliance, changes in rectal microbiome, FA details and other postoperative outcomes.

Study description

Background summary

Multicenter prospective clinical effectiveness trial, whereby current local practice (control cohort) will be subsequently compared to the results of a multi-interventional program (intervention cohort) in patients undergoing total mesorectal excision (TME) for rectal cancer. This program includes:
1. Mechanical bowel preparation with oral antibiotics
2. Tailored full splenic flexure mobilization
3. Intraoperative fluorescence using indocyanine
4. Routine CRP-measurement at day three postoperatively, CT-scan with rectal contrast on indication
5. EVAC with early transanal closure of the anastomotic defect

Study objective

To increase the one year anastomotic integrity rate in patients undergoing total mesorectal excision (TME) for rectal cancer by the routine and quality controlled implementation of a multi-interventional program.

Study design

Preoperative. 3 and 4 days postoperative. 1, 3 and 12 months postoperative

Intervention

1. Mechanical bowel preparation with oral antibiotics
2. Tailored full splenic flexure mobilization
3. Intraoperative fluorescence using indocyanine
4. Routine CRP-measurement at day three postoperatively, CT-scan with rectal contrast on

indication
5. EVAC with early transanal closure of the anastomotic defect

Contacts

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Eligibility criteria

Inclusion criteria

1) Patients with a diagnosis of primary rectal cancer with the lower border below the level of the sigmoid take-off on MRI, or regrowth in a watch and wait protocol, or undergoing completion/salvage surgery after local excision;
2) Age above 18;
3) Able to fill in questionnaires in Dutch and to come to out-patient-clinic visits;
4) Written informed consent.

Exclusion criteria

1) Patients not undergoing resection with colo-rectal/anal anastomosis;
2) Local recurrent rectal cancer;
3) Locally advanced rectal cancer requiring extended or multi-visceral excision;
4) Synchronous colonic resections;

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2020
Enrollment:	488
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	02-01-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 55903
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8261
CCMO	NL67600.018.18
OMON	NL-OMON55903

Study results