Functional outcomes and quality of life of elderly patients with rectal carcinoma

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26671

Source
Nationaal Trial Register

Brief title
FQER

Health condition

Rectal carcinoma
Stoma problems
Functional outcomes
Quality of life

Rectum carcinoom
Stoma problemen
Functionele uitkomsten
Kwaliteit van leven

Sponsors and support

Primary sponsor: Medical Centre Alkmaar
Source(s) of monetary or material Support: Initiator = sponsor

Intervention

Outcome measures

Primary outcome

What does a patient choose: resection with a primary anastomosis or with a permanent colostomy

Secondary outcome

Quality of life and functional outcomes, measured with multiple validated questionnaires

Study description

Background summary

Elderly patients who have been operated on for rectal carcinoma and received either a primary anastomosis or a permanent colostomy will be invited to participate in an evaluation study. Validated questionnaires will be sent, patients can self-administer these at home.

Mean results of these questionnaires will be grouped according to stoma status and will be shared with the patients.

There will be two time points of questionnaires.
The primary outcome will be measured during the second time point.

Study objective

The hypothesis is that a permanent colostomy in elderly patients with rectal carcinoma has no less quality of life compared to elderly patients with a primary anastomosis.

Study design

The questionnaires will be sent to eligible patients at home. There will be 2 timepoints of questionnaires.

Intervention

None. This is an evaluation study using validated questionnaires that will be self-administered by patients at home.

Contacts

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Eligibility criteria

Inclusion criteria

- histological proven rectal carcinoma

- 70 years of age at the time of operation

- elective low anterior resection between 31-12-2007 and 01-01-2014

Exclusion criteria

- acute resection

- transanal endoscopic microsurgery

- abdominoperineal resection

- diagnosed with cognitive impairment

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-04-2014
Enrollment:	80
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL4427
NTR-old	NTR4551

Register	ID
Other	METC Noord-Holland : M014-003

Study results