TRANSANAL ENDOSCOPIC MICROSURGERY VERSUS ENDOSCOPIC MUCOSAL RESECTION FOR LARGE RECTAL ADENOMAS

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In a randomized trial we will compare the cost-effectiveness and cost-utility of TEM and EMR for the resection of large rectal adenomas.

Ethical review	-
Status	Recruiting
Health condition type	Benign neoplasms gastrointestinal
Study type	Interventional

Summary

ID

NL-OMON32240

Source
ToetsingOnline

Brief title
TREND study

Condition

- Benign neoplasms gastrointestinal

Synonym
rectal adenoma, rectal polyp

Research involving
Human

Sponsors and support

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

doelmatigheid (kosten en effecten)

Intervention

Keyword: endoscopic mucosal resection, rectal adenoma, transanal endoscopic microsurgery

Outcome measures

Primary outcome

1) proportion of patients with adenoma recurrence after 3 months; 2) number of

days not spent in hospital from initial treatment until 2 years afterwards;

adenoma recurrence after 3 months is defined as treatment failure.

Secondary outcome

3) morbidity, subdivided into major (requiring surgery) and minor (requiring

endoscopic or medical intervention); 4) disease specific and general quality of

life; 5) anorectal function; 6) health care utilization and costs.

Study description

Background summary

Recent non-randomized studies suggest that extended endoscopic mucosal resection (EMR) is equally effective in removing large rectal adenomas as transanal endoscopic microsurgery (TEM). If equally effective, EMR might be a more cost-effective approach as this strategy does not require expensive equipment, general anesthesia and hospital admission. Furthermore, EMR appears to be associated with fewer complications. In a randomized trial we will compare the cost-effectiveness and cost-utility of TEM and EMR for the resection of large rectal adenomas.

Study objective

In a randomized trial we will compare the cost-effectiveness and cost-utility of TEM and EMR for the resection of large rectal adenomas.

Study design

13 Dutch expertise centers will participate in this multicenter randomized trial comparing TEM versus EMR.

Intervention

TEM: under general anesthesia a TEM tube is inserted in the rectum. With specialized instruments the adenoma will be dissected en bloc by a full thickness excision, after which the patient will be admitted to the hospital.
EMR: without sedation (or conscious sedation only), an endoscope is inserted into the rectum and the submucosa underneath the lesion will be injected with saline to lift the adenoma. With an endoscopic snare the lesion will be resected through the submucosal plane in a piecemeal fashion, after which the patient will be discharged from the hospital. Residual adenomatous disease visible during the first surveillance endoscopy at 3 months will be removed endoscopically in both strategies and is considered as part of the primary treatment.

Study burden and risks

All patients will undergo standard treatment and follow-up. The only adjustment to current clinical practice will be the randomization which determines the treatment strategy (TEM versus EMR).

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) Diagnosed with a large non-pedunculated rectal adenoma with a largest diameter of at least 3cm.
(2) The lower and upper borders of the adenoma are located at >1cm and <15cm from the anal verge, respectively.
(3) Biopsies of the lesion did not show invasive cancer.
(4) No endoscopic or endoscopic ultrasonographic suspicion for invasive cancer
(5) Synchronous colonic adenomas or cancers are excluded by colonoscopy first.
(6) The general health condition of the patient permits general/spinal anesthesia (ASA I-III).
(7) Absence of non-correctable coagulopathy
(8) Patient age of 18 years or older.

Exclusion criteria

(1) Suspicion for invasive cancer during endoscopy or endoscopic ultrasonography
(2) Proven invasive cancer with biopsies (histology)

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-02-2009
Enrollment:	186
Type:	Actual

Ethics review

Not available

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	NL23846.018.08