The sensitivity of scar-biopsies for residual colorectal adenocarcinoma after endoscopic resection with uncertain radicality.

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To evaluate the sensitivity of second-look endoscopic biopsies from the polypectomy site for residual adenocarcinoma in the surgical resection specimen.To register patients in whom exclusion criteria exist, in order to prospectively evaluate the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational invasive

Summary

ID

NL-OMON44110

Source
ToetsingOnline

Brief title
SCAPURA-study

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
Large bowel cancer

Research involving
Human

Sponsors and support

Primary sponsor: Deventer Ziekenhuis

Source(s) of monetary or material Support: Er is momenteel geen specifieke financiering voorhanden;het onderzoek wordt gefinancierd door het Deventer Ziekenhuis en het Erasmus MC. De kosten van de extra endoscopie worden niet in rekening gebracht bij patiënt / zorgverzekeraar maar zijn een offer van de afdeling MDL in het deelnemende centrum

Intervention

Keyword: Colorectal cancer, Endoscopic resection, Pathology, Rescue surgery

Outcome measures

Primary outcome

Sensitivity of second-look biopsies from the polypectomy site for residual tumor in the resected bowel. Sensitivity is determined by the number of tumor-positive biopsies divided by the number of tumor positive resection specimens.

Secondary outcome

* 90-day mortality after rescue surgery: the number of patients that died within 91 day after the operation for presumed residual adenocarcinoma*

* The sensitivity of biopsies for residual cancer in the bowel wall: the number of patients with endoscopic biopsies containing adenocarcinoma divided by the number of patients with adenocarcinoma in the resected bowel wall (regardless of regional lymph nodes)*

* The number of complications (defined according to GCP) after biopsies from the polypectomy: the number of patients with bleeding or perforation after taking biopsies from the polypectomy scar, requiring at least prolongation of treatment, or admission to hospital, or delay or speeding up rescue surgery. This up until the moment of surgery.

* The sensitivity of global endoscopic assessment of initial polypectomy as

well as scar biopsies for residual cancer: the number of patients in whom the endoscopic resection was assessed as incomplete and who also have residual cancer in the surgically resected specimen divided by the total number of patients in whom the endoscopic resection was judged to be incomplete.

* The proportion of patients with residual cancer in the resected specimen if malignancy was unsuspected during the endoscopic polypectomy: the number of patients in whom the malignancy was initially unsuspected during endoscopic polypectomy and who also have residual cancer in the surgical specimen divided by the total number of patients in whom the malignancy was initially unsuspected during endoscopic polypectomy.

* The prevalence of residual tumor at operation and postoperative morbidity and mortality in patients in whom exclusion criteria are applicable, and there for are not eligible for taking biopsies.

Study description

Background summary

Since the introduction of a nation-wide screening program on large bowel cancer, the number of endoscopically resected malignant colorectal polyps is increasing.
Unfortunately, oncological radicality is usually impossible to guarantee after endoscopic resection. Hence, additional surgical resection is carried out in a considerable number of patients.
However, in 80% of these surgical resection specimens no residual adenocarcinoma is found, nor in the bowel wall, nor in regional lymph nodes. Evidently, the endoscopic resection was sufficient. One could state that these patients have been operated in vain and that they have been exposed to considerable postoperative morbidity and mortality risks (especially in the elderly patient).

Study objective

To evaluate the sensitivity of second-look endoscopic biopsies from the polypectomy site for residual adenocarcinoma in the surgical resection specimen.
To register patients in whom exclusion criteria exist, in order to prospectively evaluate the results of operations in the Netherlands.

Study design

Prospective cross-sectional design using a multi-center approach. Patients consenting to participation will have an endoscopy shortly before operation (preferably in the operating room) to take biopsies from the polypectomy site. The results of biopsies are compared to the resected bowel.
Patients in whom biopsies have no added value, will only be registered.

Study burden and risks

Depending on the situation of the patiënt, the following may occur:

1. A second endoscopy needs to be done to tattoo the polypectomy site, or for endoscopic full-thickness resection. Participation is no extra burden. The taking of biospies is painless and takes only a few minutes.
2. No second endoscopy would be needed (regular surgery, TEM, TAMIS, polypectomy site already tattooed). Participation implies a second endoscopy. Depending on the site where the polyp has been removed, the following types of endoscopy may apply:
A. For distal tumors: a sigmoidoscopy. This implies distal bowel prep with two enemas, investigation without conscious sedation in outpatient setting.
B. For tumors proximaal to the sigmoid: colonoscopy. This implies a full bowel prep, investigation under conscious sedation and daycare admission.
The above mentioned situation is only applicable for patients having laparoscopic or transabdominal surgical resection.

The risk of a second endoscopy are generale perceived as extremely small: the endoscopy is only done to go to the polypectomy place and to take biopsies. The risk of perforation or bleeding are estimated to be below 1: 5000. Again, if risk are perceived to be elevated on the basis of the recent experience with the colonoscopy, the patient will not be included.

Patients in whom exclusion criteria exist, will only be registered without any intervention.

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

All of the following criteria should be fulfilled:;1. Age 18 or above.
2. Endoscopically removed colorectal lesion with the following pathological characteristics:
a. A moderately to well-differentiated adenocarcinoma.
b. In case of an en-bloc resection: distance between adenocarcinoma and vertical or lateral resection
margin is less than 1 mm.
c. In case of piecemeal resection: unjudgeable radicality (mostly due to loss of orientation and multiple
fragments).
d. Absence of, or unjudgeable lymphatic or vascular invasion.
e. No tumor budding (only if specifically mentioned in the pathology report).
f. No deep (> 1mm) submucosal infiltration.
3. No suspicion of dissemination on the following investigations: serum carcino-embryonic antigen,
computer tomographic (CT) scan of the abdomen and a chest X-ray; in case of a rectal tumor (less
than 15 cm from the anal verge): magnetic resonance imaging of the rectum.
4. Operation (including local transmural excision by TEM, TAMIS or eFTR*) is advised in

agreement
with the Dutch Guideline on Colorectal cancer and has been planned and agreed on by the patient.
5. Written informed consent is obtained.;*TEM: Transanal Endoscopic Microsurgical excision
TAMIS: TransAnal Minimal Invasive Surgery
eFTR: Endoscopic Full-Thickness Resection

Exclusion criteria

1. Pathology shows one or more of the following characteristics:
a. A radical en-bloc resection with a free vertical and lateral margin of * 1 mm.
b. A poorly differentiated or signet-cell containing adenocarcinoma.
c. Lymphatic or vascular invasion (if this feature is unjudgeable due to piecemeal resection, no
exclusion is done).
d.Tumor budding (only if specifically mentioned in the pathology report)
f. Deep (> 1 mm) submucosal infiltration
2. Suspicion of dissemination on investigations as mentioned in the inclusion criteria
3. Patients already receiving anti-tumor treatment (including radiotherapy for rectal cancer) for another tumor or a synchronic colorectal cancer
4. Patients in whom a second-look endoscopy would require major and unacceptable effort and / or
resources, for instance clinical admission for bowel preparation, long travel, general anesthesia,
extremely difficult to reach polypectomy site.
5. Patient is not planned for endoluminal local resection (TEM, TAMIS, eFTR)*, or standard surgery.
6. Patient is pregnant.
7. Patient does not provide written informed consent or is unable to provide such.;*TEM: Transanal Endoscopic Microsurgical excision
TAMIS: TransAnal Minimal Invasive Surgery
eFTR: Endoscopic Full-Thickness Resection

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-07-2015
Enrollment:	1080
Type:	Actual

Ethics review

Approved WMO Date:	08-06-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	31-07-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-05-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-06-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
ClinicalTrials.gov	NCT02328664
CCMO	NL51461.078.15

Study results

Date completed: 01-02-2019

Actual enrolment: 103

Summary results
Trial is onging in other countries