TAMIS vs ESD for the removal of rectal polyps.

No registrations found.

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

Summary

ID

NL-OMON20612

Source
Nationaal Trial Register

Brief title
TRIASSIC

Health condition

rectal cancer
rectal adenoma
endoscopic submucosal dissection
Transanal Minimally Invasive Surgery
endeldarm kanker
endeldarm poliep

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Cumulative recurrence rate at follow-up rectoscopy after 6 and 12 months, histologically confirmed from resected visible residual disease or, if not present, from biopsies of the scar.

Secondary outcome

• Radical (R0-) resection rate, defined as dysplasia free vertical and lateral resection margins at histology

• To compare the perceived burden of the treatment and quality of life among patients (see study procedures for questionnaires that will be used)

• Overall complication rate*

• Surgical referral rate defined as the number of patients that are referred for trans abdominal surgical management at 12 months

• Cost effectiveness at 24 months. Costs will be calculated from a hospital perspective, including costs of (repeat) surgery and hospital stay. The difference in costs will be compared to the difference in local recurrence and the difference in quality-adjusted life years (QALYs).

Study description

Background summary

Rationale: Colorectal cancer (CRC) is the second most prevalent cancer in the Netherlands, with 15,000 new cases per year and 5000 colorectal cancer related deaths. The Dutch National Colorectal Cancer screening program began in 2014 and is expected to save 1400 lives per year in the short term through early diagnosis and treatment of cancer. In the longer term it is expected to save an additional 1000 lives per year through the prevention of cancer by removing advanced polyps. In the last few years two new highly promising innovative approaches have become available for minimally invasive en bloc resection of large non-pedunculated rectal lesions. One is a new surgical technique called transanal minimally invasive surgery (TAMIS) and the other is a new endoscopic technique called endoscopic submucosal dissection (ESD). Although both techniques are standard of care in the Netherlands, a direct randomised comparison between TAMIS and ESD is lacking. Therefore, the choice for either of both therapies remains operator-dependent instead of evidence-based.

Objective: The aim of this study is to compare both procedures with regard to recurrence rates and complete (R0) resection rate, and to put this into perspective against the costs and complication rates of both strategies and the burden perceived by patients in both the short and long term.
Hypothesis: We hypothesize that ESD will be associated with longer procedure times but lower costs. For lesions that prove to be benign, we hypothesize that ESD will lead to a higher

number of R0 resections and lower recurrence rates, particularly for lesions involving the dentate line, and less serious complications than TAMIS. For lesions that prove to be invasive we hypothesize that TAMIS will have a higher R0 resection rate but that this will not translate to a reduced need for additional surgery.
Study design: Multicentre randomised controlled trial
Study population: Patients 18 years of age or older with a non-pedunculated polyp in the rectum with endoscopic features suspicious for early invasion, found during screening, surveillance or diagnostic colonoscopy.
Intervention: In the TAMIS-arm, resection will be performed using the TAMIS technique, whereas patients randomised to the ESD-arm will undergo resection using the ESD technique.

Endpoints: The primary endpoint is recurrence rate at follow-up colonoscopy at 6 months. Secondary endpoints: 1. Radical (R0-) resection rate 2. Perceived burden and quality of life, 3. Cost effectiveness at 24 months, 4. Surgical referral rate at 24 months, 5. Complication rate, 6. Recurrence rate at 24 months.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The two resection techniques investigated in this study are standard care in the Netherlands and thus will not contain any additional risks for participating patients. Certain procedures that are optional but recommended in standard care will be performed in all participating patients, including (1) Endoscopic ultrasound of the lesion, (2) MRI of the rectum and (3) biopsies of the scar at follow-up rectoscopies. Follow-up rectoscopy is standard care after resection of an adenoma, and will be performed 6 and 24 months after resection as recommended by the current Dutch guideline for colonoscopy surveillance. The questionnaires to evaluate patients' burden and quality of life are grouped as much possible to limit the frequency of questionnaires. Taken together, neither an unacceptable risk nor a direct benefit is expected for patients participating in this study. This study will increase current knowledge as to the preferred minimally invasive resection method, which is currently unknown. This is important as the detection rate of these adenomas is expected to further increase with the introduction of the Dutch CRC screening program. The study will therefore support an optimal use of healthcare resources in the future.

Study objective

We hypothesize that ESD will be associated with longer procedure times but lower costs. For lesions that prove to be benign, we hypothesize that ESD will lead to a higher number of R0 resections and lower recurrence rates, particularly for lesions involving the dentate line, and less serious complications than TAMIS. For lesions that prove to be invasive we hypothesize that TAMIS will have a higher R0 resection rate but that this will not translate to a reduced need for additional surgery.

Study design

The primary outcome (recurrent polyp) is measured after 6 months and 12 months by endoscopy.

QOL will be measured by questionnairesat baseline, 4 days, 4 weeks, 6 months and 12 months.

Intervention

In the TAMIS-arm, resection will be performed using the TAMIS technique, whereas patients randomised to the ESD-arm will undergo resection using the ESD technique.

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the ‘background’ criteria and at least one of the ‘specific’ criteria:

Background criteria

o Non-pedunculated polyp in the rectum where the bulk of the lesion is below 15cm from the anal verge found at colonoscopy

o ≥18 years old

o Written informed consent

Specific criteria

o Any degree of suspicion of early invasion: An endoscopic, ultrasound or MRI diagnosis of benign adenoma cannot be made with an estimated accuracy of >98%.

o Lesions of any size with an estimated >2% likelihood of harbouring a focus of minimally invasive (sm1) T1 carcinoma due to the presence of any one of the following features:

o LST-NG

o LST-G >4cm

o A Kudo Vi-type or Vn-type pit pattern (Vn-type pit pattern must be limited to an area of <10% of the total lesion area and <5mm in diameter)

o Type 3 blood vessels

o Presence of a large >1cm nodule within a LST-G lesion

o Large protruded-type lesions

o Irregular surface

o Easy bleeding

o Lower lying areas within the lesion suspicious for depression
LST-NG: Laterally spreading tumour non granular; LST-G: Laterally spreading tumour granular.

Exclusion criteria

o Endoscopic, ultrasound or MRI features of advanced disease (T stage >=2 or N stage >=1). Where there is discordance in the results, the optical endoscopic evaluation will be given the most weight and the case discussed by an expert panel of four study participants.

o Prior endoscopic resection attempt

o The risk exceeds the benefit of endoscopic treatment, such as patients with an extremely poor general condition or a very short life expectancy

o The inability to provide informed consent

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2019
Enrollment:	198
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 53125
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7083
NTR-old	NTR7281
CCMO	NL61603.058.18
OMON	NL-OMON53125

Study results