

ESD and TAMIS: Results from a multicenter study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23611

Source

NTR

Brief title

TBA

Health condition

Registration study
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: N/A

Intervention

Outcome measures

Primary outcome

Recurrence rate at follow-up colonoscopy at 6 and 12 months.

Secondary outcome

- En bloc resection rate, defined as macroscopic removal of the lesion in a single piece
- Radical (R0-) resection rate, defined as dysplasia free vertical and lateral resection margins at histology for benign lesions
- Radical (R0-) resection rate, defined as dysplasia free vertical and lateral resection margins at histology for invasive lesions
- Surgical referral rate at 12 months
- Complication rate

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 endoscopic technique called endoscopic submucosal dissection (ESD) and the other is a new surgical technique called transanal minimally invasive surgery (TAMIS). Although both techniques are standard care in the Netherlands, a randomized comparison between TAMIS and ESD is lacking. Therefore the TRIASSIC study (NL61603.058.18) was started; A multicenter, randomised controlled trial comparing TAMIS and ESD for resection of non-pedunculated rectal lesions. This study will further increase knowledge on the preferred minimal invasive method by prospectively collecting data of the patients refusing to be randomised in the TRIASSIC study.

Objective: The aim for this study is to assess the safety and effectiveness of both ESD and TAMIS in the rectum.

Study design: Prospective observational study

Study population: Patients eligible for inclusion for the TRIASSIC study, but refused randomization due to, for example, a distinct preference for one of the procedures. (Patients 18 years of age or older with a large non-pedunculated polyp in the rectum found during screening, surveillance or diagnostic colonoscopy)

Intervention: Resection will be performed using either the TAMIS technique or the ESD

technique.

Main study parameters/endpoints: To improve our knowledge of the safety and effectiveness for both procedures by assessing: recurrence rate at follow-up colonoscopy at 6 and 12 months. Secondary endpoints: 1. Radical (R0-) resection rate 2. Surgical referral rate at 12 months 3. Complication rate.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Both resection techniques investigated in this study are standard care in the Netherlands.

Therefore participating will not be associated with an increased risk compared to standard care. Certain procedures that are optional but recommended in standard care will be performed in all participating patients, including (1) MRI of the rectum and (2) 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 12 months after resection. Taken together neither an unacceptable risk nor a direct benefit is expected for patients participating in this study. Collecting prospective data from patients not willing to be randomized in the TRIASSIC study makes sure even more data will be collected on these relatively new minimal invasive methods, with scarce prospective data in western population, increasing our knowledge on the preferred minimal invasive method. This is important as the detection rate of these adenomas is expected to further increase with the introduction of the Dutch CRC screening program in 2014. Therefore this study will 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

Intervention

In this observational side study of the TRIASSIC trial patients will either undergo resection by the TAMIS technique or by the ESD technique.

Contacts

Public

LUMC

Nik Dekkers

0715264361

Scientific

LUMC

Nik Dekkers

0715264361

Eligibility criteria

Inclusion criteria

- Unwillingness to participate in the TRIASSIC study (Trial NL7083; NTR7281)
- Non pedunculated polyp >2cm in the rectum, where the bulk of the lesion is below 15cm from the anal verge found at colonoscopy
- ≥ 18 years old

Exclusion criteria

- Features of advanced disease or deep-submucosal invasion at optical endoscopic evaluation.
- Features of advanced disease on cross-sectional imaging. 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.
- Prior endoscopic resection attempt
- The risk exceeds the benefit of endoscopic treatment, such as patients with an extremely poor general condition or a very short life expectancy
- The inability to provide informed consent

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):	26-08-2019
Enrollment:	50
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description

N/A

Ethics review

Positive opinion	
Date:	26-08-2019
Application type:	First submission

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

NTR-new

Other

ID

NL7988

METC LUMC : N19.055

Study results

Summary results

N/A