ESD and TAMIS: Results from a multicenter study

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23611

Bron
NTR

Verkorte titel
TBA

Aandoening

Registration study
Rectal cancer
Rectal adenoma
Endoscopic submucosal dissection
Transanal Minimally Invasive Surgery
Endeldarm kanker
Endeldarm poliep

Ondersteuning

Primaire sponsor: Leiden University Medical Centre
Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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 of 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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel

Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	26-08-2019
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
N/A

Ethische beoordeling

Positief advies

Datum:	26-08-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7988
Ander register	METC LUMC : N19.055

Resultaten

Samenvatting resultaten
N/A