Multicentre, randomised controlled trial comparing TRansanal minimal InvAsive Surgery (TAMIS) and endoscopic Submucosal dIsseCtion (ESD) for resection of non-pedunculated rectal lesions.

Published: 12-12-2018
Last updated: 21-09-2024

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...

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

Summary

ID

NL-OMON53125

Source
ToetsingOnline

Brief title
TRIASSIC

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms malignant and unspecified
- Gastrointestinal therapeutic procedures

Synonym
Rectal polyps. Rectal adenoma

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: NWO,CHDR

Intervention

Keyword: Colorectal adenoma, Endoscopic Submucosal Dissection, Rectum adenocarcinoma, Transanal Minimally Invasive Surgery

Outcome measures

Primary outcome

The primary endpoint is cumulative recurrence rate at follow-up colonoscopy at

6 and 12 months

(Side-study smartwatch: the mean time to recovery after ESD and TAMIS expressed

in days.)

(Side-study MRI: accuracy of MRI in detection of muscularis mucosae disruption

as compared to the pathological ESD specimen.)

Secondary outcome

Secondary endpoints: 1. Radical (R0-) resection rate 2. Perceived burden and

quality of life, 3. Cost effectiveness at 12 months, 4. Surgical referral rate

at 12 months, 5. Complication rate, 6. Recurrence rate at 12 months. The

cost-effectiveness of TAMIS against ESD will be performed with the costs per

recurrence free patient and the cost per quality adjusted life year (QALY) as

outcome measures

(Side-study smartwatch:1. Recovery percentage within 4 weeks, 2. Average step count the weeks after ESD/TAMIS, 3. Average heart rate the weeks after ESD/TAMIS, 4. Average amount of sleep the weeks after ESD/TAMIS 5. Tolerability of the smartwatch 6. Comparison of the perceived recovery (questionnaire) with the results from the smartwatch.)

(Side-study MRI: measuring the depths of invasion of MRI compared to the ESD specimen. 2. comparing the thickness of the submucosa between the standard MRI and the MRI with submucosal injection.)

Study description

Background summary

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 projected to save 1400 lives per year in the short term through early diagnosis and treatment of cancer. In the longer term it is projected to save an additional 1000 lives per year through the prevention of cancer by removing advanced polyps. Two modalities are available for minimally invasive en bloc resection of large non-pedunculated rectal lesions, including transanal minimally invasive surgery (TAMIS) and 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.

(Side-study smartwatch: The purpose of this side-study is to further increase our knowledge on the physical recovery after ESD and TAMIS procedures. Currently, there is very limited data on the recovery period after ESD/TAMIS. This study is the first to use a smartwatch to measure the physical activity after ESD/TAMIS. Monitoring physical activity can give useful long-term outcome measures that truly reflects a patient*s recovery in their own environment.)
(Side-study MRI: the purpose of this pilot study is to examine whether submucosal voluven injection can improve standard MRI T-stage accuracy in non-pedunculated rectal lesions.)

Study 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.

(Side-study smartwatch: To compare the physical recovery time after TAMIS and ESD. Recovery is defined as: Reaching or surpassing 90% of the average step count measured at baseline for 2 consecutive days.)
(Side-study MRI: investigate the feasibility to detect disruption of the submucosa of non-pedunculated rectal lesions by MRI after submucosal voluven injection.)

Study design

Multicentre randomised controlled trial

(Side-studies: Side-studies of the TRIASSIC study)

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.

(Side-study smartwatch: 1. Wearing and synchronizing a smartwatch; focused on measuring the physical activity. 2. Completing a short questionnaire after 4 weeks.)
(Side-study MRI: 1. Rectoscopy prior to ESD for voluven injection. 2. Abbreviated MRI scan.)

Study burden and risks

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) biopsies of the scar at follow-up colonoscopies. Follow-up colonoscopy is standard care after resection of an adenoma, and will be performed 6 and 12 months after resection. The questionnaires to evaluate patient 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 the knowledge on the preferred minimally invasive resection method that is currently unknown. This is important as the detection rate of these

adenomas has increased dramatically with the introduction of the Dutch CRC screening program. The study will therefore support an optimal use of health resources in the future

(Side-study smartwatch: The burden for study participants is estimated to be low and consists of continuous wearing of the Withings Steel HR® watch, synchronizing with the HealthMate smartphone application daily and a questionnaire at the end of the study. There are no health risks or benefits associated with wearing a smartwatch.)
(Side-study MRI: injection of submucosal fluid is a safe endoscopic procedure with very low risk of bleeding. It is often used during endoscopic resection of polips. MRI scan (without contrast) is a non invasive diagnostic modality without side effects.)

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Non-pedunculated polyp >20mm in the rectum where the bulk of the lesion is below 15cm from the anal verge.
- Indication for treatment
- >=18 years old
- Written informed consent

Exclusion criteria

o Features of advanced disease or deep submucosal invasion at optical endoscopic evaluation.
o 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.
o Prior 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
(Side-study smartwatch:
• Wheelchair dependency at baseline
• Inability to wear or use the wearable device)
(Side-study MRI:
• Contra indication for MRI scan)

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-02-2019

Enrollment:	198
Type:	Actual

Ethics review

Approved WMO Date:	12-12-2018
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	25-04-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	31-07-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	25-09-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	05-10-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	10-05-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	16-01-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	16-09-2024
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20612
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL61603.058.18
Other	Trial NL7083 (NTR7281)