Prospective Registration of endoscopic Full Thickness Resection in the Netherlands

No registrations found.

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

Summary

ID

NL-OMON24864

Source
NTR

Health condition

endoscopic full thickness resection
colorectal polyp
colorectal adenoma
colonoscopy

Nederlands:
endoscopische full thickness resectie
colorectale poliep
colorectaal adenoom
coloscopie

Sponsors and support

Primary sponsor: Academic Medical Center Amsterdam
Source(s) of monetary or material Support: Investigator initiated, so no funding by commercial parties

Intervention

Outcome measures

Primary outcome

Our main study endpoint is the technical success rate of all scheduled eFTR procedures with the FTRD defined as the number of patients with a complete endoscopic en bloc resection in the Netherlands.

Secondary outcome

The following secondary study parameters are designed to further study the technical success, the applicability and the safety of all eFTR procedures in the Netherlands;

- The number of patients with histologically confirmed R0 resection defined as negative lateral and deep margins

- The number of patients with a histologically confirmed full thickness resection

- The number of eFTR procedures in which the procedure was not technical succesfull, due to the inability to reach the lesion, the inability to retract all the tissue in the FTRD and technical difficulties with the FTRD

- Number of intra procedural complications, defined as any perforation or a bleeding for which an additional intervention, defined as transfusion, admission, radiologic intervention or surgical treatment is required

- Number of patients with early (48 hours) and late (until 14 days) postprocedural complications for which additional treatment is necessary, defined as presentation at the emergency ward, transfusion, admission, repeat endoscopy, radiologic intervention or surgical treatment

- The occurrence of recurrence during follow-up colonoscopies

- Procedural time

Study description

Background summary

Most benign colorectal polyps can be endoscopically removed with conventional polypectomy techniques, including piecemeal endoscopic mucosal resection (EMR) and endoscopic submucosal dissection (ESD). However, these techniques are limited to the superficial layers of the colonic wall and although sufficient in the majority of cases, a subset of lesions cannot be treated conventionally. These difficult to remove colorectal polyps consist of large (≥40

mm) flat lesions, non-lifting lesions, or lesions located at difficult anatomic locations involving the ileocecal valve, a diverticulum or the appendiceal orifice.

In order to overcome some of the technical challenges of the endoscopic removal of complex lesions a novel endoscopic device has been developed to perform endoscopic full-thickness resection (eFTR) with immediate secure defect closure. This full-thickness resection device (FTRD, Ovesco Endoscopy, Tübingen, Germany) consists of a modified over-the-scope clip (OTSC) mounted on a cap with a preloaded snare. It has been investigated in preclinical trials and a recent clinical case series of 25 colorectal lesions. However more clinical research is needed to further investigate the clinical applicability, technical success rates and safety of performing eFTR with the FTRD. Therefore we will perform a prospective registration of all scheduled eFTR procedures with the FTRD in the Netherlands to further investigate the applicability, technical success rates and safety of this device. The technical success of all scheduled eFTR procedures in the Netherlands is defined as the number of endoscopic complete en bloc resections and the number of histologically confirmed R0 and full-thickness resection. The applicability and safety of all scheduled eFTR procedures will studied when investigating the number of scheduled eFTR procedues that were note completely performed, procedural time, complication rates and the occurrence of local recurrence during surveillance colonoscopies.

Study objective

We aim to study the applicability, safety and technical success of all scheduled eFTR procedures in the Netherlands.

Study design

01-06-2017: evaluation of 6 months inclusion period

01-01-2018: evaluation of a one year inclusion period

Intervention

There will be no formal interventions in this study, since this is a prospective registration of endoscopic full-thickness resection, wherefore the indication for this procedure is already set by an trained endoscopist.

Contacts

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Eligibility criteria

Inclusion criteria

We will prospectively include all patients who are scheduled to undergo an eFTR procedure with the FTRD performed by one of the trained endoscopists in the Netherlands.

In order to be eligible to be included in this study a patient must meet all of the following criteria:

- Scheduled to undergo eFTR procedure with the FTRD performed by one of the trained endoscopists in performing FTRD procedures in the Netherlands

Exclusion criteria

There are no formal exclusion criteria since the indication for a full thickness resection of all patients was already set by a trained endoscopist in the Netherlands.

Study design

Design

Study type: Observational non invasive

Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2017
Enrollment:	200
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL5868
NTR-old	NTR6292
Other	METC AMC : W16_262#16.308

Study results