Prospective Registration of endoscopic Full Thickness Resection in the Netherlands

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

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24864

Bron
NTR

Aandoening

endoscopic full thickness resection
colorectal polyp
colorectal adenoma
colonoscopy

Nederlands:
endoscopische full thickness resectie
colorectale poliep
colorectaal adenoom
coloscopie

Ondersteuning

Primaire sponsor: Academic Medical Center Amsterdam
Overige ondersteuning: Investigator initiated, so no funding by commercial parties

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2017
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL5868
NTR-old	NTR6292
Ander register	METC AMC : W16_262#16.308

Resultaten