Long term outcomes of Endoscopic Intermuscular Dissection for stage I rectal carcinomas

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That intermuscular dissection of polyps suspected of deep submucosal invasive carcinoma can result in the radical (R0) excision of > 85% of the carcinomas, and that the risk of local recurrence is below 4%.

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

Samenvatting

ID

NL-OMON24409

Bron
Nationaal Trial Register

Verkorte titel
EID

Aandoening

T1 rectal cancer

Ondersteuning

Primaire sponsor: UMC Utrecht
Overige ondersteuning: xxxx

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1) The proportion of histology confirmed (R0) resections of deep submucosal (T1) invasive rectal carcinomas with R0 defined as a minimal of 0.1 mm tumor free deep resection margin
2) The 3 and 5 years recurrence rate defined as either a local regrowth, LNM during or distant metastasis during follow-up of an R0 resection of a T1 CRC without the histological risk factors lymphovascular invasion, tumor budding or poor differentiation.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: With the introduction of the national colorectal cancer (CRC) screening program the number of T1 CRCs have increased. Approximately 80% of these T1 CRCs are located in the sigmoid and rectum. The risk of lymph node metastasis (LNM) is approximately 10-15% for non-pedunculated T1 CRCs in the rectum. Therefore 80% could potentially be cured with a minimal invasive local resection. Achieving a decrease in unnecessary radical rectal surgery is desired, since the long term burden of a total mesorectal excision (TME) on the patient's quality of life is high (stoma, low anterior resection syndrome etc). In the past, deep submucosal invasive cancer (Sm3) was considered a risk factor for LNM, but recent observations showed that in the absence of lymphovascular invasion and tumor budding, the risk of LNM is only 1.3-1.7%, which equals the mortality risk of TME. Endoscopic intermuscular dissection (EID) is a new endoscopic technique designed as an adaptation of the well-known classical ESD technique. Instead of dissecting the lower third of the submucosal space in classical ESD, EID aims to dissect the intermuscular space between the circular and the longitudinal part of the m. propria (instead of the submucosa) in the rectum. In this adaptation EID can achieve a radical resection (R0) for deep submucosal invasive T1 CRCs, thereby potentially obviate the need for radical surgery.

Objective: The aim of this study is to prospectively evaluate the long-term outcome of endoscopic intermuscular dissection for a deep invasive rectal T1 carcinoma.

Study design: Prospective cohort study

Study population: All consecutive adult patients with an endoscopic intermuscular dissection for a suspected deep submucosal invasive T1 rectal carcinoma.

Main study parameters: R0-resection, curative resection rate, local recurrence rate, stoma rate after completion TME, quality of life

Doel van het onderzoek

That intermuscular dissection of polyps suspected of deep submucosal invasive carcinoma can result in the radical (R0) excision of > 85% of the carcinomas, and that the risk of local recurrence is below 4%.

Onderzoeksopzet

Recurrence rate at 3 and 5 years

Onderzoeksproduct en/of interventie

Intermuscular dissection between the circular and longitudinal part of the m. propria of the rectum

Contactpersonen

Publiek

UMC Utrecht
LMG Moons

0614599001

Wetenschappelijk

UMC Utrecht
LMG Moons

0614599001

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Adult patients with a suspected T1 CRC with deep submucosal invasion based on optical diagnosis, using JNET 3, NICO III or Hiroshima C2-C3 classification, or > 40% with the OPTICAL model.
- A T1 rectal cancer located at or under the sigmoid take-off on the MRI
- At least 5 mm between the dentate line and the carcinomatous part of the polyp
- Written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Age < 18 years
- Unable to complete quality of life questionnaires at baseline and 1e follow-up, or sign informed consent
- Treatment of a AJCC stage III or IV CRC within the last 5 years
- A suspicious peri-rectal lymph node of > 9 mm on the preprocedural MRI.
- A T1 CRC extending above the sigmoid take-off on MRI

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 nog niet gestart
(Verwachte) startdatum:	01-05-2020
Aantal proefpersonen:	140
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

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	NL8409
Ander register	METC UMC Utrecht : xxx

Resultaten