Diagnostic and therapeutic implications of endoscopic resection in EUS-staged T2 esophageal adenocarcinoma

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An endoscopic reassessment by an expert therapeutic endoscopist in patients with a cT2N0M0 esophageal adenocarcinoma, will result in a significant proportion of patients downstaged to a pT1 lesion, thereby avoiding unnecessary esophagectomy if a...

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

Samenvatting

ID

NL-OMON26531

Bron
NTR

Verkorte titel
DECREASE

Aandoening

Esophageal Adenocarcinoma (EAC), Esophagectomy, Slokdarmkanker, Endoscopic Ultrasound

Ondersteuning

Primaire sponsor: Erasmus Medical Center Rotterdam
Overige ondersteuning: Erasmus Medical Center Rotterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To prospectively evaluate the value of an endoscopic reassessment of patients with an initial diagnosis of a cT2 EAC by an experienced therapeutic endoscopist, followed by ER of the lesion if deemed possible. Expressed as the number of lesions that are downstaged to a T1 lesion after reassessment and endoscopic resection.

Toelichting onderzoek

Achtergrond van het onderzoek

The current study will prospectively evaluate the value of an endoscopic reassessment of patients with an initial diagnosis of a cT2 esophageal adenocarcinoma by an experienced therapeutic endoscopist, followed by endoscopic resection of the lesion if deemed possible. Expressed as the number of lesions that are downstaged to a T1 lesion after reassessment and endoscopic resection.

Doel van het onderzoek

An endoscopic reassessment by an expert therapeutic endoscopist in patients with a cT2N0M0 esophageal adenocarcinoma, will result in a significant proportion of patients downstaged to a pT1 lesion, thereby avoiding unnecessary esophagectomy if a curative endoscopic resection can be achieved.

Onderzoeksopzet

Time frame: approximately 1 year

Onderzoeksproduct en/of interventie

To study the resectability of an esophageal adenocarcinoma, patients will undergo an endoscopic re-assessment by high resolution endoscopy. This is a standard procedure; no new interventions will be used.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients aged > 18 years, with a biopsy proven esophageal adenocarcinoma, staged as a cT2N0M0 lesion.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Presence of metastasize disease

- Presence of (cytology proven) lymph node metastasis

- Presence of a stenosis, inhibiting the passage of a gastroscope

- Presence of esophageal varices (inhibiting endoscopic resection)

- Known or suspected esophageal perforation

- Anti-coagulant therapy (apart from aspirin or NSAID) that cannot be discontinued prior to ER, or uncorrectable hemostatic disorders.

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:	01-05-2018
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	18-07-2018
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	NL7181
NTR-old	NTR7371
Ander register	: MEC-2018-1061

Resultaten