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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26531

Source
Nationaal Trial Register

Brief title
DECREASE

Health condition

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

Sponsors and support

Primary sponsor: Erasmus Medical Center Rotterdam
Source(s) of monetary or material Support: Erasmus Medical Center Rotterdam

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

To prospectively evaluate the number of lesions that are within currently accepted criteria for endoscopic resection

Study description

Background summary

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.

Study objective

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.

Study design

Time frame: approximately 1 year

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

- 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.

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):	01-05-2018
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion

Date:	18-07-2018
Application type:	First submission

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	NL7181
NTR-old	NTR7371
Other	: MEC-2018-1061

Study results