PreCap-study

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23426

Source
NTR

Brief title
PreCap

Health condition

Barrett's esophagus; early cancer; high grade dysplasia; endoscopic resection.

in Dutch: Barrett slokdarm, vroegkanker, hooggradige dysplasie, endoscopische resectie

Sponsors and support

Primary sponsor: Academic Medial center Amsterdam, the Netherlands
Source(s) of monetary or material Support: Boston Scientific

Intervention

Outcome measures

Primary outcome

Phase I

1)Maximum diameter of the resection specimens retrieved with the CaptivatorTM -and DuetteTM devices.

Phase II

1)Percentage of successful endoscopic resection (i.e. resection of all lesion delineation markings)

Secondary outcome

Phase I

1)Difference in the number of device or procedure related complications, such as bleeding or perforation, experienced with the CaptivatorTM device compared to the DuetteTM device.

2)Visibility of the CaptivatorTM device and the DuetteTM device (pre- and post-procedure).

3)Ease of endoscopic resection

4)Procedure time

Phase II

1)Number and severity of any acute (during procedure) or early (0-48 hours) device or procedure related complications such as bleeding or perforation during endoscopic resection with the CaptivatorTM device. Complications are registered only if they are clinically significant.

2)Presence of any late complications (> 48 hours) such as bleeding or perforation during endoscopic resection with the CaptivatorTM device. Complications are registered only if they are clinically significant.

3)Procedure time

Study description

Background summary

Rationale: Endoscopic resection (ER) is the core modality in endoscopic therapy for early esophageal neoplastic lesions (i.e. high grade dysplasia [HGD] or early carcinoma) in Barrett's esophagus (BE). Histopathological assessment of the resection specimen provides the opportunity to select patients suitable for further endoscopic treatment with additional ER or ablative therapy. Recently, a new MultiBand Mucosectomy (MBM) device (CaptivatorTM EMR, Boston Scientific Corporation, Natick, MA, USA) has been developed which may have advantages over the current MBM device (DuetteTM, Cook Medical, Limerick, Ireland) by

improved visualization, passage of accessories, and suction power due to different trigger cords and cap.
Objective: The aim of this study is to assess the safety and efficacy of the new CaptivatorTM EMR device.

Study design: This study will be executed in two phases. Phase I of this study is a prospective randomized trial comparing the CaptivatorTM EMR and the DuetteTM MBM device for which 3-6 patients will be included; phase II is a prospective pilot series with the CaptivatorTM EMR for which 5 patients will be included.

Study population: For phase I adult male and female patients scheduled for esophagectomy will be included. For phase II adult male and female BE patients with known early esophageal neoplastic lesions scheduled for endoscopic resection will be included.

Intervention (if applicable): In phase I, ERs with the CaptivatorTM and DuetteTM device will be performed directly pre-esophagectomy in the upper healthy part of the esophagus. In phase II, all ERs will be performed with the CaptivatorTM EMR device instead of the DuetteTM device.

Main study endpoints: For phase I the primary outcome is the maximum diameter of the resection specimens retrieved with the CaptivatorTM EMR- and DuetteTM devices. For phase II the primary outcome is the percentage of successful endoscopic resections (i.e. resection of all lesion delineation markings).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: In phase I, the additional risk with participation is related to the longer sedation time. Patients will not be exposed to significant device associated complications because all the study patients will directly undergo an esophagectomy after the ER procedure. In phase II, patients will undergo a MBM procedure. Since the new CaptivatorTM EMR device is very similar to the current DuetteTM device, no additional risks for the MBM procedure are expected.

Study objective

Endoscopic resection of Barrett's neoplasia with the Captivator EMR device is effective and safe

Study design

Phase I

Time 0: studyendoscopy prior to esophagectomy. After completion of studyendoscopy: end of study

Phase II

Time 0: treatment endoscopy

Time 2 (after 48 hours): telephone call

Intervention

Phase I:

Endoscopic resection with Captivator EMR device and with Duette EMR device (currently used EMR device) of esophageal tissue prior to esophagectomy

Phase II:

Endoscopic resection of Barrett's neoplasia with Captivator EMR device

Contacts

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Eligibility criteria

Inclusion criteria

Phase I

1.Age 18-80 years

2.Subject is scheduled for esophagectomy

3.Subject is willing to participate, fully understands the content of the informed consent form, and signs the informed consent form.

Phase II

1.Age 18-80 years

2.Barrett’s esophagus with a visible abnormality and biopsy-proven high grade dysplasia and/or early cancer

3.Lesion with a maximum size of 4 cm in longitudinal length and 50% of the circumference.

4.No suspicion of submucosal invasion, based on the macroscopic appearance and/or endosonography

5.No signs of lymph node and/or distant metastasis on endosonography and CT-scanning of the thorax and abdomen.

6.Patient is scheduled for endoscopic resection of present BE neoplasia

7.Subject is willing to participate, fully understands the content of the informed consent form, and signs the informed consent form.

Exclusion criteria

Phase I

1.Subject has previously undergone endoscopic therapy in the intended treatment zone, including (but not limited to) cryospray therapy, laser treatment, photodynamic therapy, endoscopic mucosal resection, radiofrequency ablation or argon plasma coagulation.

2.Presence of esophageal stenosis limiting access to the intended treatment zone.

3.Scarring by other causes of the intended treatment zone.

4.Subject refuses or is not able to provide written informed consent.

Phase II

1.Subject has previously undergone endoscopic therapy in the intended treatment zone, including (but not limited to) cryospray therapy, laser treatment, photodynamic therapy, endoscopic mucosal resection, radiofrequency ablation or argon plasma coagulation.

2.Presence of esophageal stenosis limiting access to the intended treatment zone.

3.Scarring by any cause of the intended treatment zone.

4.Subject refuses or is not able to provide written informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-07-2015
Enrollment:	11
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	20-07-2015
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	NL5146
NTR-old	NTR5286
Other	METC AMC : 2015_043

Study results

Summary results
Published in surgical endoscopy