

Efficacy and safety of a new EMR device for early neoplasia in the Barrett's esophagus.

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The aim of this study is to assess the safety and efficacy of the new Captivator™ EMR kit.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON41826

Source

ToetsingOnline

Brief title

PreCap-studie

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym

esophageal cancer, esophageal neoplasia

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: grant van Boston Scientific Medical Corporation Endografts

Intervention

Keyword: Barrett esophagus, Early esophageal neoplasia, endoscopic mucosal resection, multiband mucosectomy

Outcome measures

Primary outcome

Phase I

1) Maximum diameter of the resection specimens retrieved with the Captivator

EMR - and Duette 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 Captivator™ 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 Captivator™ device.

Complications are registered only if they are clinically significant.

3) Procedure time

Study description

Background summary

Endoscopic resection (ER) is the core modality in endoscopic therapy for early esophageal neoplastic lesions (i.e. high grade dysplasia [HGD] or early carcinoma). Histopathological assessment of the resection specimen provides the opportunity to select patients suitable for further endoscopic treatment with additional ER or ablative therapy.

The ER-cap technique was the first widely used resection technique.¹⁻³ However, this procedure is technically demanding, particularly when multiple resections (i.e. piecemeal) are required. A more user friendly alternative to the ER-cap method is the multi-band mucosectomy (MBM) technique (Duette™, Cook, Limerick, Ireland).⁴⁻⁷ This modification of a variceal band ligator comprises a control handle mounted at the proximal end of the accessory channel, connected by a trigger cord to a transparent cap with six rubber bands that is placed on the tip of the endoscope. The target area is sucked into the cap without prior submucosal injection, followed by the release of a rubber band and resection of the created pseudopolyp by a hexagonal snare. This suck-band-snare procedure may be repeated six times per MBM-kit.

In Barrett's neoplasia MBM achieves comparable success rates for effective piecemeal resection compared to the ER-cap technique. Furthermore, complications rates (i.e. perforation or bleeding) are low, and MBM is quicker and cheaper than ER-cap.⁸⁻¹⁰

Yet, the Duette™ MBM system has some disadvantages. First, it provides a reduced endoscopic visualisation due to the presence of the black rubber bands on the distal attachment cap, which limit the circumferential visualization and absorb most of the endoscopic light. Reduced visualisation may lead to incomplete endoscopic resections and may hamper the management of complications such as bleeding.

Secondly, the release strings of the Duette™ system are relatively thick and therefore further limit the endoscopic view. Furthermore, due to the fibrous structure of the strings, they will absorb the mucous and blood suctioned through the working channel of the endoscope during the procedure. As a result, suction will become less powerful and passage of accessories through the working channel alongside the release strings becomes more difficult. Recently, a new MBM-device (Captivator™ EMR, Boston Scientific Corporation, Natick, MA, USA) has been developed which may overcome the disadvantages of the Duette™ system by improved visualization, passage of accessories, and suction power due to different trigger cords and cap.

Study objective

The aim of this study is to assess the safety and efficacy of the new Captivator™ EMR kit.

Study design

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

The study will be performed in a single centre, tertiary referral centre (Academic Medical Centre, Amsterdam, The Netherlands) for the endoscopic treatment of early esophageal neoplasia.

The aim is to perform both phases in the 6-9 months after approval of the IRB.

Intervention

Endoscopic resection with the Captivator™ device.

Study burden and risks

Phase I: Study patients will be sedated 20-30 minutes longer compared to patients who do not participate in this study. The additional risk with participation is therefore 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.

Phase II: patients will undergo a MBM procedure. Since the new Captivator™ EMR device is very similar to the current Duette™ device and the Captivator™ device is basically a combination of two well-known devices that have been proven safe. Therefore, no additional risks for the MBM procedure are expected.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

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 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:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	27-07-2015
Enrollment:	11
Type:	Actual

Medical products/devices used

Generic name: Captivator™ EMR (multiband mucosectomy EMR device)
Registration: Yes - CE intended use

Ethics review

Approved WMO
Date: 03-07-2015
Application type: First submission
Review commission: METC Amsterdam UMC

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
CCMO	NL48527.018.15