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

Published: 03-07-2015
Last updated: 13-04-2024

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

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| **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 Coorporation Endogrants

## 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 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**

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 (DuetteTM, 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 DuetteTM 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 DuetteTM 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 (CaptivatorTM EMR, Boston Scientific Corporation, Natick, MA, USA) has been developed which may overcome the disadvantages of the DuetteTM 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 CaptivatorTM EMR kit.

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

## Intervention

Endoscopic resection with the CaptivatorTM device.

## Study burden and risks

Phase I: Studypatients will be sedated 20-30 minutes longer compared to patients who do not participate in this study. the additional risk with participation is therefor 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 CaptivatorTM EMR device is very similar to the current DuetteTM device and the CaptivatorTM device is basically a combination of two well-know devices that have been profen safe. Therefor, 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

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|---|---|
| Generic name: | CaptivatorTM EMR (multiband mucosectomy EMR device) |
| Registration: | Yes - CE intended use |

## Ethics review

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|---|---|
| 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 |