A Feasibility Trial to Evaluate Endoscopic Removal of early esophageal neoplasia using Endoscopic Submucosal Dissection with LumenR Esophageal RetractorTM (LER), a Modified Esophageal Overtube

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25650

Source
Nationaal Trial Register

Brief title
LumenR feasibility study

Health condition

early esophageal neoplasia
vroege slokdarmkanker

Sponsors and support

Primary sponsor: AMC Amsterdam
Source(s) of monetary or material Support: LumenR LLC: supplies devices

Intervention

Outcome measures

Primary outcome

1. Experienced technical ease/difficulty of the LumenR retractor assisted ESD relative to the anticipated ease/difficulty (by two endoscopist) of removing the lesion with standard ESD. This will be measured using a -5 to +5 visual analogue scale with zero denoting an equal ease/difficulty of the LumenR retractor assisted ESD and standard ESD.

2. Difference in duration of time of the estimated time (by two endoscopists experienced in performing ESD) required for standard ESD and the actual time required for resection by LumenR retractor assisted ESD.

Secondary outcome

1. Number of patients with complete en bloc endoscopic resection using LumenR-assisted ESD.

2. Number of patients with a histological R0-resection.

3. Duration of time required to resect the lesion of interest.

4. Rate of acute complications (occurring during the procedure).

5. Rate of early complications (occurring <48 hours of the procedure).

6. Rate of late complications (occurring >48 hours and <30 days after the procedure).

7. Amount of solution used for submucosal injection to lift the target tissue.

Study description

Background summary

Barrett's esophagus is a condition in which a normal esophageal epithelium is replaced with the intestinal epithelium, which may transform into dysplasia or adenocarcinoma. The Barrett's esophagus is diagnosed with upper gastrointestinal (GI) endoscopy and biopsy. The exact prevalence of the Barrett’s esophagus is unknown, but it is estimated that it affects 1.6 to 6.8 percent of people.1 Men develop Barrett’s esophagus twice as often as women, and Caucasian men develop this condition more often than men of other races.2 The average age at diagnosis is 55.3 The exact cause of Barrett's esophagus is not known. However, gastroesophageal reflux disease (GERD) increases the chances of developing the condition.4. Treatment options for Barrett's esophagus include a surveillance endoscopy, endoscopic ablative therapies, endoscopic mucosal or submucosal resection, and surgery. When Barrett’s

esophagus is found to harbor a high dysplasia or an early adenocarcinoma endoscopic treatment is preferred over surgical treatment. Endoscopic treatment consists of endoscopic resection of endoscopically visible abnormalities supplemented with ablation therapy for flat type residual Barrett's mucosa. The purpose of the endoscopic resection is to remove the most involved part of Barrett's segment with histological correlation and to render the residual Barrett's segment flat for subsequent ablation therapy. Histological staging is imperative for optimal patient selection: only well/moderately differentiated mucosal cancers without lymphovascular invasion are amendable for curative endoscopic treatment whereas patients with submucosal invading lesions, poorly differentiated cancers, or lymphovascular invasion should be treated by additional esophagectomy given their risk for local lymph node metastasis. Endoscopic resection of early neoplasia in Barrett's esophagus is mainly performed using cap-based techniques. These resection techniques allow en bloc resection of lesions up to approximately 15-mm in diameter. Larger lesions require removal in multiple pieces (i.e. piecemeal resection). After piecemeal resection assessment of the radicality of the lateral margins is generally not feasible. From an oncological standpoint complete resection in one piece (i.e. en bloc resection) is preferred since it allows optimal histological staging including the assessment of the lateral resection margins. Despite these theoretical advantages of en bloc resection over piecemeal resection, most early Barrett's lesions are still removed by the cap based resection techniques in piecemeal. There are two reasons for this: 1) endoscopic resection en bloc of larger lesions requires the use of a technique known as endoscopic submucosal dissection (ESD). ESD is technically complicated procedure in which the outer margin of the lesion is incised followed by careful dissection of submucosal space underneath the lesion until it can be removed en bloc.5-8 The ESD technique has been developed in Japan but in the Western world experience with this technology is limited. Compared to piecemeal resection, ESD is more time consuming and carries a higher risk of complications. In addition, ESD in Barrett's esophagus is considered to be more difficult and risky than standard ESD indications (i.e. esophageal squamous neoplasia and early gastric cancer) because of the movement of distal esophagus due to respiration, esophageal motility and the contractions of the heart, the higher rate of scarring of the submucosal compartment due to longstanding gastroesophageal reflux, and the larger diameter of the submucosal blood vessels; 2) large scale multicenter studies have shown that piecemeal resection combined with endoscopic ablation therapy results in high success rates for eradicating neoplasia (>95%) with a low 5-year recurrence rate of neoplasia (<5%)9,10; 3) most of the histological staging that is so important for proper risk assessment can be just as well done on piecemeal resection specimens as on specimens obtained en bloc. For these reasons, recent European guidelines on the use of ESD in the gastrointestinal tract have considered ESD in Barrett's to be only an optional resection technique. For squamous neoplastic lesions of the esophagus, ESD is the preferred resection technique. Most Barrett's expert centers therefore, currently restrict the use of ESD to lesions to the following indications 1) lesions with a bulky intraluminal component; 2) lesions with a large area suspicious for invasive cancer; or 3), or lesions suspected of submucosal invasion. In these lesions, cap-based endoscopic piecemeal resection may compromise the radicality of the deeper resection margin and/or the histological assessment of the cancer. Despite the conservative adaption of ESD for Barrett´s neoplasia, most experts agree that if ESD of Barrett's lesions would be just as easy, safe and effective as current piecemeal techniques, all Barrett's lesions would be resected en bloc by ESD. The challenge therefore is in developing an ESD technique to overcomes the technical challenges of ESD: the lack of triangulation and counter traction

during dissection of the submucosal space, the instability of the working field do to peristalsis, respiration and heartbeat, and the lack of independent maneuverability of devices and optical inspection. LumenR RetractorTM (LER) is a modified esophageal overtube, which has expandable chamber on its distal end. This overtube is loaded on top of regular endoscope and when it is expanded inside the esophagus, it creates a stable platform improving visualization and access to the target lesion. In addition, the expandable chamber has an extra working channel, allowing use of commercially available grasping forceps to retract the tissue in various directions and creating effects of triangulation. In addition, the expandable chamber, retraction tools and endoscope can operate independently, which significantly facilitate dissection of the target tissue and could make endoscopic resection of early Barrett's neoplasia and early squamous esophageal neoplasia simple and safe. Our hypothesis is that the use of the modified esophageal overtube (LumenR) will simplify endoscopic removal of the target tissue with clear margins, will decrease the time needed to complete the procedure and will decrease the rate of complications (i.e. bleeding, perforation, etc).

Study objective

Our hypothesis is that the use of the modified esophageal overtube (LumenR) will simplify endoscopic removal of the target tissue with clear margins, will decrease the time needed to complete the procedure and will decrease the rate of complications (i.e. bleeding, perforation).

Study design

day 0, 3, 10 and 90.

Intervention

Endoscopic submucosal dissection using the LumenR-overtube

Contacts

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Eligibility criteria

Inclusion criteria

To be enrolled in this study, subjects must meet the following entry criteria.

1. Age from 18 to 90 years.

2. An early esophageal neoplastic lesion with a biopsy-based histological diagnosis of either early Barrett's neoplasia (i.e. high-grade dysplasia or early adenocarcinoma) or early esophageal squamous neoplasia (i.e. high-grade dysplasia or early squamous carcinoma).

3. The lesion of interest should appear endoscopically resectable according to the discretion of two experienced interventional endoscopists with specific interest in the field of early upper GI neoplasia treatment.

4. The lesion of interest should have a maximum longitudinal extent of 80-mm (no minimum length is required).

5. The lesion of interest should have a maximum circumferential extent of less than 75%.

6. Patients with early Barrett's neoplasia should have at least one of the following endoscopic features, which may compromise the radicality of the deeper resection margin and/or the histological assessment of the cancer when using cap-based endoscopic piecemeal resection:

a) a bulky intraluminal component;

b) lesions with an area suspicious for invasive cancer >20-mm;

c) lesions suspicious for submucosal invasion; or

d) poor differentiation grade (if known beforehand).

7. Subject is able to understand the risks and benefits of participating in the study and must be willing to sign and date the Informed Consent Form for this study approved by the Institutional Review Board (IRB.)

Exclusion criteria

1. Clear presence of invasion into the proper muscle layer of the esophagus on endoscopic ultrasound.

2. Local lymph node metastasis on EUS with positive fine needle aspiration.

3. Esophageal narrowing restricting passage of a 20-mm Savary bougieovertube prior to the procedure.

4. Patients with uncorrectable bleeding disorders (INR more than 1.5, platelet count less than 50,000).

5. Patients with esophageal varices

6. Patients with allergies for materials from which the device is constructed: PVC, Nitinol, Watershed, Polycarbonate, and PTFE.

7. Subjects who received any experimental drug or device within the previous three months.

8. Patients who are not able to sign informed consent, or do not understand the content of the IC.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2015
Enrollment:	10
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

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	NL5312
NTR-old	NTR5421
Other	NL54041.018.15 : 2015_187

Study results

Summary results
none