Multi-band mucosectomy plus BARRx Radiofrequency Ablation for Eradication of High-Grade Dysplasia and Early Cancer in Barrett's oesophagus.

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The purpose of this project is to evaluate the combination of ER using the multi-band mucosectomy technique and RFA (HALO360/HALO90) for treatment of Barrett*s esophagus with HGD or early cancer. This will be a multi-centre European study including...

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

Summary

ID

NL-OMON30022

Source
ToetsingOnline

Brief title
RFA-EURO-I

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
Barrett's oesophagus, heartburn

Research involving
Human

Sponsors and support

Primary sponsor: BARRx Medical Inc

Source(s) of monetary or material Support: Ministerie van OC&W,BARRx Medical Inc;540 Oakmead Parkway;Sunnyvale CA;USA

Intervention

Keyword: Barrett's oesophagus, High grade dysplasia, multi-band-mucosectomy, radiofrequency ablation

Outcome measures

Primary outcome

Primary clinical outcome parameters will be assessed at t=6 and t=12 months:

1. Rate of total histological eradication of HGD and EC

2. Rate of total endoscopic eradication of Barrett*s mucosa

3. Rate of total histological eradication of Barrett*s mucosa

Secondary outcome

1. Acute and late complications of MBM and RFA

2. Percentage of surface regression of Barrett*s epithelium

3. Number of treatment sessions required

Study description

Background summary

Patients with Barrett's Esophagus (BE) undergo endoscopic surveillance to detect malignant progression in their esophagus at an early and curable stage. Patients with High Grade Dysplasia (HGD) are considered to have a significantly increased risk for development of esophageal cancer (i.e metachronous cancers). For patients with HGD that have visible abnormalities in their BE it is therefore advised to extensively biopsy these abnormalities and preferably to have them removed by endoscopic resection (ER) to exclude an invasive cancer before deciding on further management. The most widely practiced ER technique is the ER-cap technique in which the target lesion is lifted by submucosal fluid injection, usually using diluted adrenaline (1:100.000). Subsequently, a transparent cap is attached to the endoscope. This cap has a distal ridge that allows positioning of a special ER-snare. The lesion is sucked into the cap and

the snare is closed thus creating a pseudo-polyp that is then removed using electrocoagulation. In one study a local remission of 98% was achieved by ER (19). This procedure is safe and serious complications are rare (20). Minor complications, such as minor bleeding, occur in 9% of the cases and usually are easily managed endoscopically (19). Drawback of the ER-cap technique is that it a technically demanding procedure that requires submucosal injection, placement of the ER-snare in the ridge of the ER-cap, and a new ER-snare for every resection.Recently, a prototype ER device (Wilson-Cook Medical, Limerick, Ireland) has become available that may allow for removal of multiple specimens without the need for a high-level of endoscopic experience. This device uses a modified variceal band ligator that has multiple rubber bands attached to a standard variceal ligation cap. This technique has several advantages, with the current MBM prototype, up to six consecutive resections can be performed (the instruments holds six rubber bands) without withdrawing the endoscope. This reduces the time required for the procedure as well as cost and patient discomfort.

A drawback of ER is that only focal lesions are removed whereas the remaining Barrett's mucosa left untreated. Since this mucosa has a *field defect* new neoplastic lesions may develop elsewhere in the BE during follow up. Studies have shown that after ER, 30% of the patients may develop such metachronous lesions. Some centers have therefore advocated the use of adjuvant treatment with additional ablation therapy to minimize this risk.

At the Academic Medical Centre in Amsterdam, over 50 patients with HGD/EC have been recently treated by stepwise radical endoscopic resection (SRER) in which the whole Barrett*s segment is removed through consecutive ER sessions. This not only reduces the potential risk of metachronous lesions, but also provides a complete tissue sample for histological correlation. Drawback of SRER is that it requires multiple treatment sessions and carries an increased risk (30-70%) for esophageal scarring and esophageal stenosis.

Endoscopic ablation therapy is used for treatment of selected patients with HGD in a Barrett*s esophagus. Endoscopic ablation therapy is also used as an adjuvant treatment after EMR for early Barrett*s cancer to treat any hidden areas of synchronous neoplasia and/or to reduce the rate of recurrences during follow-up.

Photodynamic therapy (PDT) and Argon Plasma Coagulation (APC) are the most widely used techniques in this respect. These techniques are, however, associated with significant drawbacks: PDT is expensive and uncomfortable to the patient.Radiofrequency ablation (RFA) is a new promising endoscopic ablation technique that may overcome some of the aforementioned drawbacks of PDT and APC.At the Academic Medical Centre in Amsterdam, 11 patients with LGD/HGD have been recently treated with HALO-360 RFA to ablate their dysplasia and Barrett*s mucosa. Treatment was without significant complications. Complete eradication of all dysplasia was achieved in 91% after the initial treatment period (2 endoscopic treatment sessions allowed with a 2 months interval) and in all patients the esophagus healed without scarring or stenosis.

Study objective

The purpose of this project is to evaluate the combination of ER using the multi-band mucosectomy technique and RFA (HALO360/HALO90) for treatment of Barrett*s esophagus with HGD or early cancer. This will be a multi-centre European study including three tertiary referral centres for the endoscopic treatment of early Barrett*s neoplasia. An arbitrary number of 12 patients per centre will be included.

Study design

Twelve patients with a Barrett's esophagus and high grade dysplasia or early cancer will be included at each center (AMC, Evangelisches Krankenhaus, L'Hopital Erasm). Patients will undergo an endoscopic resection with the MBM technique for a focal lesion.
Additionally two or three Radio Frequency Ablation sessions will follow. At six and twelve months follow-up primary and secondary endpoints will be assessed.

Intervention

Patients will be treated for their Barrett's esophagus with dysplasia or early cancer. Patients will undergo an endoscopic resection with the MBM technique for a focal lesion followed by RadioFrequency Ablation to ablate the remaining Barrett's mucosa.

Study burden and risks

For endoscopic resection usually the ER-cap or MultiBandMucosectomy is performed. These procedures are safe and serious complications are rare. Minor complicartions such as minor bleeding, occur in 9% of the cases and usually are easily managed endocopically.
Stepwise radical endoscopic resection (SRER) is used as treatment for eradication of the barrett's esophagus. Drawback of SRER is that it requires multiple treatments which are time consuming per session and uncomfortable to the patient. Moreover, SRER carries an increased risk (30-70%) for esophageal scarring and stenosis.
Radiofrequency Ablation is a new promising technique which is significant less invasive than SRER. We anticipate a 5% rate of acute complications and a 5% late stenosis rate due to esophageal scarring.

Contacts

Public
BARRx Medical Inc

540 Oakmead Parkway
Sunnyvale, CA 94085
USA
Scientific
BARRx Medical Inc

540 Oakmead Parkway
Sunnyvale, CA 94085
USA

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Patients in the age of 18-85 years with HGD or EC in a Barrett*s esophagus.
2. An endoscopically visible abnormality containing HGD a/o EC with a circumferential extent <50%, a linear extent of <2 cms, and no endoscopic signs suggestive of submucosal invasion.
3. Pretreatment biopsies reviewed by an expert local pathologist.
4. EUS without signs of deep submucosal invasion or suspicious local lymph nodes.
5. Normal CT-scan of thorax and abdomen using 5-mm slices (optional for patients with only HGD in their pretreatment biopsies and in their ER specimens).
6. Presence of LGD or HGD in the residual Barrett*s segment after ER of the aforementioned endoscopically visible abnormality.
7. Informed written consent.

Exclusion criteria

1. Patients with a Barrett*s segment >12 centimeters.
2. Any prior endoscopic treatment of Barrett*s neoplasia.
3. After the ER but before RFA: positive vertical resection margins in any of the ER

specimens.
4. After the ER but before RFA: remaining visible abnormalities containing HGD or EC after ER (additional ER is allowed).
5. After the ER but before RFA: esophageal stenosis due to scarring after the previous ER, defined as resistance in passing a therapeutic gastroscope.
6. After the ER but before RFA: any invasive cancer in biopsies obtained at high-resolution endoscopy after ER but before the RFA treatment.
7. After the ER but before RFA: absence of LGD and HGD in biopsies obtained at high-resolution endoscopy after ER but before the RFA treatment.
8. After the ER but before RFA: an interval > 3 months after the last high-resolution endoscopy with biopsies between ER and RFA.
9. After the ER but before RFA: an interval < 6 weeks after the ER.
10. Patients unable to give informed consent.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2006
Enrollment:	12
Type:	Anticipated

Medical products/devices used

Generic name:	HALO360 and HALO90 radiofrequency ablation system
Registration:	No

Ethics review

Approved WMO

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	NL13314.018.06