Improving practicality of radiofrequency ablation for eradication of Barrett*s mucosa: a randomized trial comparing two different treatment regimens for focal ablation using the HALO90 System

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To develop a simplified HALO90 ablation protocol at the same energy level and with compared efficacy and safety as the current protocol.

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

Summary

ID

NL-OMON35335

Source
ToetsingOnline

Brief title
Optimization of HALO90 ablation of Barrett's mucosa

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
Dysplasia in Barrett's, precancerous esophageal mucosa

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Barrx Medical Inc;Sunnyvale CA;USA

Intervention

Keyword: Barrett's esophagus, Dysplasia, HALO90, Radiofrequency ablation

Outcome measures

Primary outcome

Outcome parameters will be assessed after a single HALO90 treatment session:

- Rate of complete removal of BE islets

- Percentage of endoscopically visual surface regression of BE epithelium after

2 months as scored by two endoscopists blinded to the treatment regimen

Secondary outcome

non

Study description

Background summary

Radiofrequency ablation (RFA) is a new endoscopic ablation technique that has been shown to be an easy, safe and effective treatment modality for complete eradication of Barrett*s esophagus (BE) containing early neoplasia. Compared to PDT and APC, RFA seems to be more easy to use, better tolerated by patients, and is not associated with esophageal stricturing or the occurrence of buried Barrett*s.
In RFA, the Barrett*s segment is ablated by radiofrequency energy through two specially designed devices for circumferential and focal ablation respectively. The HALO360 System consists of a balloon which contains a spindle-shaped electrode on its outer surface. Balloons with different diameters and lengths of electrodes are available. For focal ablation a cap-based electrode, the HALO90 System is used. The instruments have been developed by BÂRRx Medical Inc, Sunnyvale CA, USA and are FDA and EC approved for ablation of Barrett*s mucosa.

Currently, most patients undergo primary circumferential ablation with a balloon based electrode, the HALO360 System, followed by multiple focal ablation sessions using a cap-based electrode, the HALO90 System. During these HALO90 procedures, residual islands undergo 2 separate ablation passes, each pass with two sequential *hits* at 15 J/cm2. In between these 2 ablation passes the ablation zone is cleaned of its coagulum and the HALO90 catheter is removed in order to clean the surface of the electrode. The actual HALO90 ablation is relatively easy to perform. Subsequent cleaning of the ablation zone, removal, cleaning and reintroduction of the catheter are, however, impractical and uncomfortable to the patient. We propose a simplified HALO90 ablation procedure in which cleaning of the ablation zone is left out, thereby reducing the number of introductions with the endoscope and the HALO ablation device.
We hypothesize that this simplified HALO90 ablation procedure results in an easier and faster ablation procedure, while maintaining efficacy and safety.

Study objective

To develop a simplified HALO90 ablation protocol at the same energy level and with compared efficacy and safety as the current protocol.

Study design

Patients scheduled for HALO90 ablation for BE (with or without neoplasia) after prior circumferential ablation using the HALO360 System for BE with flat low-grade dysplasia (LGD) or high-grade dysplasia (HGD) or for BE (with or without neoplasia) after prior endoscopic resection (ER) for lesions containing HGD or and early cancer are being asked for inclusion in the study.

Treatment protocol: HALO90 procedure
The BE is evaluated for the presence of strictures and the presence of residual BE mucosa using high-resolution white light (WL) endoscopy and narrow band imaging (NBI). The number, size (maximum and minimum diameter) and localization (insertion depth of the endoscope and orientation in the endoscopic field) of all islands and BE tongues are documented on video recordings and still images (WL + NBI). Islands are then numbered sequentially from proximal to distal.
A minimum of one and a maximum of four islands per HALO90-procedure will be randomized. Tongues and *large islands* (larger than the total surface of four adjacent HALO90 treatment zones) are excluded from randomization. The treatment regimen to which the first island is randomized will be the first treatment regimen performed.
Eligible islands will be randomized to either the standard *double-double* regimen at 15 J/cm2 (two ablation passes each with two *hits* at 15 J/cm2 and with cleaning of the ablation zone in between the two passes), or a *single-triple* ablation at 15 J/cm2 (single ablation with three *hits* at 15 J/cm2 and no subsequent cleaning).
Islands will be randomized in couples (islands 1-2 and 3-4, or 1-2 and 3, or

1-2), always randomizing one island out of a couple and automatically redirecting the other island of the couple to the other treatment regimen, to guarantee an even spread of both treatment regimens within a HALO90-procedure. This means that all patients with two or more eligible BE islands will undergo both the standard HALO90 ablation regimen and the simplified HALO90 regimen.

Standard HALO90 ablation regimen:

After mapping and randomization the Barrett*s segment is flushed with the mucolytic agent acetylcysteine (1%) followed by flushing with tap water. The endoscope is removed and the proximal esophagus is thoroughly inspected to exclude the presence of a Zenker*s diverticulum that may make subsequent introduction of the HALO90 cap difficult or dangerous.
The HALO90 cap is attached to the tip of the endoscope at the twelve o*clock position and introduced into the distal esophagus. Visible islands are then treated with 2x15 J/cm2 (40 Watt)): the cap is brought into close contact with the target area and is then activated. The endoscope and the cap are kept in position and immediately a second ablation of the same area is performed. After ablation of an island, the endoscope is gently removed from the mucosa and rotated to remove the coagulum by suctioning through the endoscope.
If the squamocolumnar junction (SQJ) has an irregular appearance the SQJ is treated circumferentially, allowing an overlap of 5-10 mm between the adjacent ablations. After all islands and Z-line have been ablated in this manner, the necrotic debris is cleaned off by a combination of suctioning and irrigating tap water. In addition, the HALO90 cap can be used to gently push off the coagulum from the ablation zone. Subsequently, the ablated areas are cleaned by vigorous flushing of water through a spraying catheter. After emptying the stomach, the endoscope is removed, the HALO90 electrode is cleaned and then reintroduced to ablate all treated areas again with 2x15 J/cm2 (40 Watt).
Simple HALO90 ablation regimen:
In the simplified HALO90 ablation regimen the target area is treated with 3x15 J/cm2 (40 Watt) *single-triple* regimen without cleaning in between the ablations. Using this regimen the HALO90 ablation device mounted on the endoscope needs to be introduced only once.

Consequences for eligible patients
In this study design individual islands instead of individual patients are randomized. This ensures that the two ablation regimens are compared under equal circumstances (it reduces variability due to interpatient differences) and increases the power of the study since generally multiple islands are eligible per patient.
This does imply, however, that patients who have more than one eligible island will undergo both the standard 2x2x15 J/cm regimen (for treatment of islands randomized to this regimen as well as non-eligible islands and Z-line) AND the simplified 3x15 J/cm regimen (for treatment to this regimen). This requires an additional introduction of the endoscope with the HALO90 catheter and a maximum

of 2 ablations. It is estimated that this will prolong the procedure by less than 5 minutes. The total duration of a HALO90 ablation using the standard regimen is approximately 35 minutes.

Follow-up
At two months, the first post-HALO90-treatment endoscopy will be performed with narrow band imaging. Endpoints will be scored at this time. Still images are made of any residual columnar epithelium (WL + NBI) at the sites of the previously randomized and treated isles. Percentage of endoscopically visible surface regression will be scored by two endoscopists, blinded for the administered treatment regimens, using images taken directly before HALO90 treatment and at the first post-HALO90-treatment endoscopy.
When complete eradication of BE has not been achieved, further treatment will be according to current RFA guidelines.

Outcome Parameters
Outcome parameters will be assessed after a single HALO90 treatment session:
- Rate of complete removal of BE islets
- Percentage of endoscopically visual surface regression of BE epithelium after 2 months as scored by two endoscopists blinded to the treatment regimen.

Intervention

Eradication of Barrett's mucosa.

Study burden and risks

Study patients will have an extra introduction of the endoscope with cap.
During the study treatment, patients will be treated with 2 different HALO90 catheters, one will be used for the current protocol and one will be used for the single triple regime.
The ablation procedure will be prolongated by less than 5 minutes.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ
Nederland
Scientific
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Scheduled HALO90 ablation for BE (with or without neoplasia) after prior circumferential ablation using the HALO360 System for BE with flat low-grade dysplasia (LGD) or high-grade dysplasia (HGD) or for BE (with or without neoplasia) after prior endoscopic resection (ER) for lesions containing HGD or and early cancer.
- One or more BE islands with a minimum size of 5-mm.
- Written informed consent

Exclusion criteria

Patients with endoscopically active inflammation in the treatment zone.
- Esophageal stenosis preventing advancement of the endoscope with the HALO90 catheter.
- Patients unable to give informed consent.

Study design

Design

Study phase:	2
Study type:	Interventional

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-09-2008
Enrollment:	64
Type:	Actual

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	NL25032.018.08