A Randomised Trial comparing Surveillance with Radio-Frequency Ablation of Barrett*s Esophagus with Low-Grade Dysplasia; the SURF-study

Published: 13-10-2006
Last updated: 20-05-2024

The purpose of this project is to perform a randomized trial comparing BARRX ablation with endoscopic surveillance for patients with a Barrett*s esophagus containing low-grade dysplasia. This study will also assess the effect of RFA ablation in...

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

Summary

ID

NL-OMON35588

Source
ToetsingOnline

Brief title
Radiofrequency ablation vs surveillance

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
Barrett's esophagus, precancerious condition

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 94085;USA

Intervention

Keyword: Barrett's esophagus, Low-grade dysplasia, Radiofrequency ablation, surveillance

Outcome measures

Primary outcome

Rate of high-grade dysplasia and early cancer during two year follow-up

Secondary outcome

1. Rate of total histological eradication of LGD

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

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

4. Number of procedures and costs

5. Acute and late complications of RFA

6. Percentage of surface regression of Barrett*s epithelium

Study description

Background summary

Patients with low-grade dysplasia (LGD) in their Barrett esophagus are considered to have a significantly increased risk for development of esophageal cancer (i.e. synchronous cancer). The reported risk varies between 16% to 28% for patients in whom two or more pathologists have agreed on the diagnosis of low grade dysplasia. In addition, the presence of LGD is also a risk factor for the presence of more advanced lesions elsewhere in the Barrett segment that may have been overlooked at the initial endoscopy.
Patients with LGD are therefore kept under more close observation and/or undergo more frequent endoscopic surveillance (every 6 to 12 months).
Endoscopic ablation therapy is used for treatment of selected patients with high-grade dysplasia (HGD) and early cancer in a Barrett*s esophagus. In addition, several groups have also treated LGD-patients with different ablation techniques in the past. After PDT and APC, a substantial number of patients

have residual Barrett*s epithelium and small areas of intestinal metaplasia and/or dysplasia may remain hidden underneath neosquamous mucosa. Anecdotal reports of submucosal cancers that occurred during follow-up after PDT and APC have been reported.Radiofrequency ablation (RFA) is a new promising endoscopic ablation technique that may overcome some of the aforementioned drawbacks of PDT and APC.
In RFA, the Barrett*s segment is ablated by radiofrequency ablation through a specially designed balloon which contains a spindle shaped electrode on its outer surface. Balloons with different diameters and lengths of electrodes are available. The instrument has been developed by BARRx Inc, California, USA and FDA approval is pending for ablation of non-dysplastic Barrett*s mucosa.
Studies have shown that RFA allows for quick, simple and effective superficial ablation of the esophageal mucosa. Compared to PDT and APC, RFA seems to be more easy to use and requires two or three treatment session with * in theory-less esophageal scarring and a lower chance of for developing esophageal stenosis

Study objective

The purpose of this project is to perform a randomized trial comparing BARRX ablation with endoscopic surveillance for patients with a Barrett*s esophagus containing low-grade dysplasia. This study will also assess the effect of RFA ablation in eradication of genetic oncogenic abnormalities at the epithelial level.

Study design

This study will be performed as a follow-up study on a multi-centre imaging study in Barrett*s patients with LGD in the Amsterdam region. For this study 120 Barrett*s patients with LGD will be identified from the regional Barrett*s registration project. This imaging study is a randomized trial comparing high resolution endoscopy with high resolution endoscopy using autofluorescence endoscopy and narrow band imaging and includes patients that have had a consensus diagnosis of low-grade dysplasia after review of all their biopsies by an expert panel of pathologists.
Patients selection Pilot study I
Inclusion criteria:
- Patients in the age of 18-85 years with LGD in a Barrett*s esophagus.
- LGD in biopsies obtained from the Barrett*s esophagus in the preceding 12 months and after revision of the pathology slides by at least one of the study pathologists.
- Informed written consent.
Exclusion criteria:
- Patients with a Barrett*s segment >12 centimeters.
- Any endoscopic visual abnormality detected by high-resolution white light endoscopy.

- High-grade dysplasia or invasive cancer in any of the biopsies obtained at prior endoscopies.
- Any prior endoscopic treatment of Barrett*s neoplasia.
- Patients unable to give informed consent.

Schedule
Pre assessment
- At least one high-resolution endoscopy with biopsies according to the Seattle protocol (at least 6 months prior to randomisation) and cyto-brushes.
- Revision of histopathology by two expert pathologists.
Study: in case randomized to RFA
- T=0 months: first RFA-treatment (HALO-360 RFA balloon).
- T=2 months: endoscopy ± RFA. For isolated islands with a maximum length of 2 cm and less than 50% of the circumference RFA will be performed with the HALO-90 RFA device. For larger areas of residual Barrett*s mucosa, RFA will be performed using the HALO-360 RFA balloon. It is expected that the majority of patients will require some form of additional RFA.
- T=4 months: endoscopy ± RFA. For isolated islands with a maximum length of 2 cm and less than 50% of the circumference RFA will be performed with the HALO-90 RFA device. For larger areas of residual Barrett*s mucosa, RFA will be performed using the HALO-360 RFA balloon. It is expected that the minority of patients will require some form of additional RFA and that this mainly will be done using HALO-90 RFA device.
- T=6 months: high-resolution endoscopy with lugol staining and biopsies from neosquamous epithelium (4QBx/2 cm, standard biopsy forceps). In case biopsies are obtained from areas with visible Barrett*s mucosa, additional treatment using the catheter based RFA device is allowed.
- T=12 months: endoscopy with lugol staining and biopsies from neosquamous epithelium (4QBx/2 cm, standard biopsy forceps) and cyto-brushes.
- From the second year: annual endoscopy with lugol staining and biopsies from neosquamous (4QBx/2 cm, standard biopsy forceps) and cyto-brushes.
Study: in case randomized to surveillance
- T=0 months: endoscopic surveillance using high-resolution endoscopy with biopsies according to the Seattle protocol (4QBx/2 cm, standard biopsy forceps) and cyto-brushes.
- T=6 months: endoscopic surveillance using high-resolution endoscopy with biopsies according to the Seattle protocol (4QBx/2 cm, standard biopsy forceps).
- T=12 months: endoscopic surveillance using high-resolution endoscopy with biopsies according to the Seattle protocol (4QBx/2 cm, standard biopsy forceps) and cyto-brushes.
- From the second year: annual endoscopic surveillance using high-resolution endoscopy with biopsies according to the Seattle protocol (4QBx/2 cm, standard biopsy forceps) and cyto-brushes

Intervention

Patients, who are randomized for radiofrequency ablation will be treated for low-grade dysplasia in Barrett's esophagus with radiofrequency ablation.

Study burden and risks

25% of patients with low grade dysplasia may be expected to develop high-grade dysplasia or early cancer during two years of follow-up.
For patients in the RFA group this rate is expected to be less than 5%.
In addition, we anticipate a 5%rate of acute complications and a 5% rate of late stenosis 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

Low-grade dysplasia in Barrett's slokdarm

Exclusion criteria

Patients with a Barrett's segment of >12cm

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-06-2007
Enrollment:	120
Type:	Actual

Medical products/devices used

Generic name:	HALO 360 and HALO 90 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	NL13682.018.06