A randomized trial comparing radiofrequency ablation with step-wise radical endoscopic resection for treatment of Barrett*s esophagus with high-grade dysplasia or early cancer.

Published: 30-10-2006
Last updated: 20-05-2024

The purpose of this study is to find answers for the following questions:1. Is BARRX ablation a good alternative to step-wise radical endoscopic resection for patients with a Barrett*s esophagus with high-grade dysplasia or early cancer in terms of...

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

Summary

ID

NL-OMON30042

Source
ToetsingOnline

Brief title
Radiofrequency ablation vs SRER-study

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms malignant and unspecified

Synonym
Barrett's oesophagus, precancerous condition of the esophagus

Research involving
Human

Sponsors and support

Primary sponsor: BARRx Medical Inc
Source(s) of monetary or material Support: BARRx Medical Inc;540 Oakmead Parkway;Sunnyvale;CA 94085;USA

Intervention

Keyword: Barrett's oesophagus, Dysplasia, radio frequency ablation, Stepwise radical endoscopic resection

Outcome measures

Primary outcome

- total histological eradication of HGD and/or EC.

- total endoscopic eradication of Barrett*s mucosa.

- total histological eradication of Barrett*s mucosa.

Secondary outcome

- acute and late complications of RFA

- Percentage regression of Barrett's mucosa on the surface.

- Changes in 24 hour impedantie-measurments and micro-manometry.

Study description

Background summary

Patients with a BE are kept under endoscopic surveillance to detect malignant progression in their esophagus at an early and curable stage.
Endoscopic ablation therapy is used for treatment of selected patients with 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. Photodynamic therapy (PDT) and Argon Plasma Coagulation (APC) are the most widely used techniques in this respect. Both are, however, associated with significant drawbacks. PDT is expensive and uncomfortable to the patient. APC is most effective at higher energy settings where it may be associated with severe complications such as perforation and stenosis. 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. There have been anecdotal reports of submucosal cancers that occurred during follow-up after PDT and APC. PDT is not used in our department due to bad results and the discomfort for our patients.
Radiofrequency ablation (RFA) is a new promising endoscopic ablation technique that may overcome some of the aforementioned drawbacks of PDT and APC.The probe is manufactered by BARRx Inc, California, USA. In the USA the probe has ben tested in multiple studies concerring Barrett's oesophagus. SRER (Stepwise Radical Endoscopic resection) is the standard treatment in Europe for HGD and/or early carcinoma in a Barrett's segment. By stepwise radical endoscopic resection, SRER, the Barrett's mucosa including dysplasia or early carcinoma is radicaly resected in consecutive sesions.
This study will tell us whether RFA is a suitable procedure to treat patients with a barrett's oesophagus containing dysplastic cells.

Study objective

The purpose of this study is to find answers for the following questions:
1. Is BARRX ablation a good alternative to step-wise radical endoscopic resection for patients with a Barrett*s esophagus with high-grade dysplasia or early cancer in terms of efficacy, early complication rate, late complication rate and the presence of buried Barrett*s?
2. Does BARRX ablation preserve the functional integrity of the distal esophagus as measured with 24 hour impedance measurement and micro-manometry.

Study design

This study is a randomized open trial in which 40 patients with a Barrett*s esophagus with high-grade dysplasia or early cancer will be randomized to BARRX ablation or SRER. Visible endoscopic lesions will be removed with EMR prior to randomization.
10 patients in both groups will undergo sophisticated functional testing of the esophagus before and six months after treatment using impedance planimetry and manometry.

Intervention

In RFA, the Barrett*s segment is ablated by radiofrequency ablation through a specially designed balloon (HALO360) 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 BÂRRx Inc, California, USA and is FDA approved for ablation of Barrett*s mucosa. Studies have shown that HALO360-RFA allows for quick, simple and effective superficial ablation of the esophageal mucosa.
By stepwise radical endoscopic resection, SRER, the Barrett's mucosa including

dysplasia or early carcinoma is radicaly resected in consecutive sesions.

Study burden and risks

Step-wise radical endoscopic resection will require three to four procedures, will be associated with an acute complication (mainly acute bleeding) during one of these procedures in approximately 50% of patients, will be associated with dysphagia during follow-up in 50% of patients and will effectively eradicate high-grade dysplasia and early cancer in all patient but will be associated with Barrett*s in 5 to 10% of patients.
BARRX ablation is expected to eradicate all Barrett's mucosa, have a 5 to 10% rate of buried Barrett*s and be associated with acute complications in 5% of patients and the development of stenosis in 5% of patients.

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

- Patients in the age of 18-85 years with HGD/EC in a Barrett*s esophagus.
- Pretreatment biopsies and ER specimen reviewed by the study pathologist (Prof. D. F. ten Kate).
- In case pretreatment diagnosis is made on biopsy material: biopsies should be obtained at two separate occasions of which the most recent occasion is less than six months prior to inclusion in the study.
- In case of previous endoscopic en-bloc resection of focal lesions: the ER specimen should have negative deeper resection margins and no invasive cancer at the lateral margins.
- In case of previous endoscopic piece meal resection of focal lesions: all ER specimens should have negative deeper resection margins and the patient should have had two separate endoscopies showing no residual invasive cancer in the remaining Barrett*s mucosa.
- Normal EUS
- Informed written consent.

Exclusion criteria

- Patients with a Barrett*s segment >5 centimeters.
- Any endoscopic visual abnormality detected by high-resolution endoscopy at the RFA procedure.
- Invasive cancer in any of the biopsies obtained at two different mapping endoscopies after ER but before RFA.
- Any prior endoscopic treatment of Barrett*s neoplasia other than ER.
- Patients unable to give informed consent.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2006
Enrollment:	40
Type:	Anticipated

Medical products/devices used

Generic name:	HALO360 en Halo90-system;Radiofrequency Balloon Device
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	NL12728.018.06