# Endoscopic Resection plus BÂRRX Radiofrequency Ablation for Eradication of Barrett's Mucosa containing High-Grade Dysplasia and Early Cancer. First European Multi-Centre Cohort Study.

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruitment stopped |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON27256

**Source**
NTR

**Brief title**
EURO-I

**Health condition**

Barrett's cancer, Barrett's dysplasia, Barrett's esophagus, Radiofrequency ablation, Endoscopic mucosa resection, Barrett's neoplasia, Endoscopic resection

### Sponsors and support

**Primary sponsor:** Academic Medical Center (AMC), Department of Hepato- and Gastroenterology
**Source(s) of monetary or material Support:** BÂRRX Medical Inc. Sunnyvale, California, US

### Intervention

## Outcome measures

### Primary outcome

Primary clinical outcome parameters 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

Secondary outcome parameters:

1. Acute and late complications of ER and RFA

2. Percentage of surface regression of Barrett's epithelium

3. Number of treatment sessions required to eradicate all Barrett's mucosa

# Study description

### Background summary

The purpose of this project is to evaluate the combination of ER, circumferential RFA using the HALO-360 system, and focal RFA using the HALO-90 system for the treatment of BE with HGD or EC. This will be the first multi-centre European study including 3 tertiary referral centres for the endoscopic treatment of early Barrett's neoplasia, in Amsterdam, Brussels and Düsseldorf. An arbitrary number of 10 patients per centre will be included.

### Study objective

We hypothesize that endoscopic resection (ER) of endoscopically visible abnormalities followed by stepwise circumferential and focal radiofrequency ablation (RFA) of the residual Barrett esophagus (BE) will effectively remove the high-grade dysplasia (HGD) and early cancer (EC) and will completely remove all Barrett's mucosa without significant complications.

### Study design

Treatment:

- T=0, at inclusion: ER of focal abnormalities, followed by biopsies of the residual Barrett's segment during the same procedure.

- Between 3 months to 1 week prior to RFA:
high-resolution endoscopy with biopsies according to the Seattle protocol.

- T=6 weeks: first RFA-treatment (HALO-360) (delay with a maximum of 12 months after ER is allowed, provided that HRE with 4QBx/2 cm is performed at least twice, the last within 3 months to 1 week prior to RFA).

- T=12 weeks: endoscopy ¡À RFA. It is expected that the majority of patients will require some form of additional 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 <10% of patients will require a second ablation with the HALO-360 system. Those patients who undergo a second HALO-360 treatment are amendable for two additional HALO-90 treatments.

- T=18 weeks: endoscopy with/without 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. 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.
Follow-up

- T=6 months: endoscopy with either lugol staining or narrow band imaging with biopsies from neosquamous epithelium 4Q/2 cm, immediately below the neo-squamocolumnar junction (min. 4 Bx) and any residual/ recurrent Barrett's mucosa. Patients with sustaining Barrett's epithelium will be treated with ER. Followed by a follow-up endoscopy after 2 months.

- T=12 months: endoscopy with either lugol staining or narrow band imaging with biopsies from neosquamous epithelium 4Q/2 cm, immediately below the neo-squamocolumnar junction (min. 4 Bx) and any residual/ recurrent Barrett's mucosa.

- From the second year: annual endoscopy with either lugol staining or narrow band imaging with biopsies from neosquamous epithelium 4Q/2 cm, immediately below the neo-squamocolumnar junction (min. 4 Bx) and any residual/ recurrent Barrett's mucosa.

**Intervention**

ER of visible lesions and EC followed by RFA of the residual Barrett's epithelium.

# Contacts

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# Eligibility criteria

## Inclusion criteria

Inclusion criteria:

1. Patients in the age of 18-85 years with HGD or EC in a BE.

2. An endoscopically visible abnormality containing HGD a/o EC and no endoscopic signs suggestive of submucosal invasion.

3. Patients with no visible abnormalities and a pretreatment diagnosis of HGD are also eligible. These patients will not undergo an ER and are directly amendable for RFA treatment.

4. Pretreatment biopsies reviewed by the study pathologist.

5. EUS without signs of deep submucosal invasion or suspicious local lymph nodes.

6. Normal CT-scan of thorax and upper 1/3 of the abdomen using 5-mm slices (only for patients with invasive cancer in their pretreatment biopsies or ER specimens).

7. Informed written consent.

## Exclusion criteria

Exclusion criteria:

1. Patients with a Barrett's segment >12 centimeters.

2. Any prior endoscopic treatment of Barrett's neoplasia.

3. Any prior endoscopic dilatation for esophageal stenosis.

4. Positive vertical resection margins, deep submucosal invasion (T1sm2), poorly or undifferentiated cancer (G3 or G4), or lymphatic/vascular invasion in any of the ER specimens.

5. Remaining visible abnormalities suggestive of possible submucosal ingrowth: type 0-Is, type 0-III or otherwise according to the discretion of the endoscopist.

6. Symptomatic dysphagia or esophageal dilatation after the ER.

7. Invasive cancer in any of the biopsies obtained at high-resolution endoscopy after the ER: biopsies should be reviewed in Amsterdam before patients are excluded based on this criterion.

8. An interval > 3 months between the last high-resolution endoscopy with biopsies and RFA.

9. An interval < 6 weeks between ER and RFA.

10. Patients unable to give informed consent.

# Study design

## Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Other |
| Allocation: | Non controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-07-2006 |
| Enrollment: | 30 |

Type: Actual

## Ethics review

Positive opinion
Date: 05-09-2008

Application type: First submission

## 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 | NL1374 |
| NTR-old | NTR1434 |
| Other | : MEC 06/189 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd |

## Study results

**Summary results**
N/A