A multi-centre randomized trial comparing Radiofrequency Ablation with Radical Endoscopic Resection for treatment of Barrett's Esophagus with High-grade Dysplasia or Early Cancer.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21764

Source
Nationaal Trial Register

Brief title
AMC-IV

Health condition

Barrett esophagus; high-grade dysplasia; high-grade intraepithelial neoplasia; intramucosal cancer; Barrett neoplasia; intestinal metaplasia.
Barrett slokdarm; hooggradige dysplasie; hoogradige intraepitheliale neoplasie; Barrett neoplasie; intestinale metaplasie.

Sponsors and support

Primary sponsor: BÂRRX Medical Inc.
540 Oakmead Parkway
Sunnyvale, CA 94085
Source(s) of monetary or material Support: BÂRRX Medical Inc.
540 Oakmead Parkway
Sunnyvale, CA 94085

Intervention

Outcome measures

Primary outcome

1. Rate of total histological eradication of HGD and/or 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 RER/RFA

2. Percentage of surface regression of Barrett's epithelium

3. Costs of materials and procedures

Study description

Background summary

We will perform a randomized trail comparing RER and RFA for the treatment of patients with Barrett's esophagus <5 cm containing high-grade dysplasia or early cancer, to investigate which treatment regimen is superior in terms of efficacy, early complication rate, late complication rate and the presence of buried Barrett's.

Study design

- T= 0: inclusion: first RER/RFA.

- T= 6 weeks: second RER/RFA.

- T=12 weeks: third RER/RFA.

- T=18 weeks: final RER/RFA.

- T=24 weeks: assessment of primary outcome parameters by endoscopy with lugol staining and biopsies.

Follow-up

- First year: every 6 months: endoscopy with lugol staining and biopsies below neo-squamocolumnar junction, residual Barrett's mucosa and neosquamous epithelium.

- From second year: annual endoscopy with lugol staining and biopsies below neo-squamocolumnar junction, residual Barrett's mucosa and neosquamous epithelium.

Intervention

Stepwise radical endoscopic resection (RER), or radiofrequency ablation (RFA)

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients with biopsy proven HGD or EC in a Barrett's esophagus in at least 2 endoscopic procedures prior to randomization, of which the last was within 3 months of randomization.

2. Age between 18 and 85 years.

3. Type I, IIa, IIb or IIc lesions

4. Maximum size of visible lesions: length < 3 cm, circumferential extend <50%.

5. No signs of deep submucosal infiltration on endoscopic inspection and EUS.

6. No signs of metastatic disease on endoscopic ultrasound (EUS) or CT-scan of thorax and abdomen (CT is only required for those with cancer in biopsies or EMR specimens).

7. Informed written consent.

Exclusion criteria

1. Length of Barrett's esophagus > 5 cms.

2. Deep submucosal infiltration („dT1sm2) in the endoscopic resection specimen.

3. Significant stenosis (not allowing passage of a therapeutic endoscope) after the initial EMR and prior to RFA.

4. Presence of invasive cancer in biopsies prior to RFA.

5. 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:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2006
Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion

Date:	12-06-2008
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	NL1290
NTR-old	NTR1337
Other	: B-206
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A