Single step treatment using radiofrequency ablation and endoscopic resection for Barrett esophagus containing early neoplasia in an endoscopically visible abnormality.

No registrations found.

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

Summary

ID

NL-OMON29052

Source
NTR

Health condition

Endoscopic resection (ER) and radiofrequency ablation (RFA) are effective treatment modalities for high-grade dysplasia (HGD) and early cancer (EC) in Barrettâ€™s esophagus (BE). ER is, however, a technically complicated procedure with a significant risk of complications. The most frequent late complication is the occurrence of esophageal stenosis, especially for cases that require widespread resection. RFA effectively removes BE mucosa but has only been used for flat type mucosa without visible abnormalities since these require ER for effective removal and staging.
Compared to ER, RFA is a relatively easy endoscopic procedure with a low risk of complications and no significant esophageal scarring. The combined treatment of ER and RFA currently requires two separate treatment sessions. Esophageal scarring after ER may, however, hamper the efficacy and safety of subsequent RFA sessions. After ER, it may be more difficult to bring the ablation balloon in full contact with the remaining BE. In addition, widespread ER may cause so much stricturing that inflation of the balloon catheter may cause esophageal laceration. For this reason most studies on the combined treatment with ER and RFA have restricted the maximum extent of ER prior to RFA to < 50% of the circumference and <2 cm in longitudinal length. However, this rule of thumb does not allow

for combined endoscopic treatment with ER and RFA in patients with larger visible abnormalities.

Sponsors and support

Primary sponsor: -
Source(s) of monetary or material Support: BARRX Medical, Sunnyvale (CA), USA

Intervention

Outcome measures

Primary outcome

1. The percentage of BE regression at 3 months follow-up after the combined ER and RFA procedure;

2. The rate of acute (i.e. < 3 days) complications after therapeutic procedures;

3. The rate of late (such as esophageal stenosis) complications occurring during the treatment phase or during follow-up.

Secondary outcome

1. The rate of complete remission of HGD and EC in all biopsies obtained at 12 months follow-up;

2. The rate of complete remission of BE, defined as the endoscopic absence of columnar lined epithelium upon inspection with NBI and the absence of intestinal metaplasia in all biopsy specimens obtained at 12 months follow-up;

3. The number of endoscopic therapeutic procedures;

4. The frequency, severity, and duration of patient's symptoms after the first therapeutic session as assessed with standardised questionnaires and patient diaries;

5. Maximum depth of injury (a) complete epithelial ablation, (b) maximum depth of ablation assessed as epithelium, lamina propria, muscularis mucosa, submucosa ('ablation' defined as any sign of irreversible injury: coagulum, loss of cellular architecture, and loss of nuclei).

Study description

Background summary

A pilot 24 patients treated with endoscopic resection (ER) and radiofrequency ablation (RFA) in a single treatment session, looking at feasibility, efficacy and safety.

Study objective

For BE patients with visible lesions containing high-grade dysplasia (HGD) or early cancer (EC) upon biopsy, a single session treatment in which the BE is first ablated using radiofrequency ablation (RFA) followed by the endoscopic resection (ER) of the visible abnormality is feasible and safe. This allows for a combined treatment which otherwise would require 2 separate procedures but more importantly, it preserves the diagnostic and therapeutic efficacy of ER but prevents that RFA is hampered by esophageal scarring after the ER.

Study design

1. 0 months: Combined ER and RFA procedure;

2. 3 months: Follow-up endoscopy with subsequent treatment;

3. 12 months: Assessment of primary endpoints.

Intervention

Endoscopic treatment with RFA and ER in a single endoscopic session in patients with a BE containing visible abnormalities with HGD or EC upon biopsy.

All patients will undergo a circumferential RF ablation using the HALO360+ system, followed by endoscopic resection of any visible abnormality in the BE during the same procedure. Prior to the ablation, the area to be resected will be marked by placing electrocoagulation markers. After the ablation, the delineated area will be resected using either the multi-band mucosectomy technique of the ER-cap technique. The second ablation session is scheduled after 3 months followed by 2-monthly ablation sessions until all endoscopically visible BE has been removed.

Contacts

Public
Academic Medical Center
Bldg. C2-210, Meibergdreef
J.J.G.H.M. Bergman

Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5669111
Scientific
Academic Medical Center
Bldg. C2-210, Meibergdreef
J.J.G.H.M. Bergman
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5669111

Eligibility criteria

Inclusion criteria

1. Age between 18 and 85 years inclusive;

2. BE with a minimal circumferential extent of 2 cm;

3. An endoscopically visible abnormality of type 0-I, 0-IIa, 0-IIc or a combination thereof, irrespective of its size;

4. A biopsy proven histological diagnosis of HGD and/or EC on two separate endoscopic sampling procedures;

5. HGD, G1 or G2 cancer in the endoscopic resection specimens, without involvement of the deeper resection margins, no lymphatic invasion, and a maximum infiltration depth into the submucosa <500Âµm;

6. Written informed consent.

Exclusion criteria

1. Any prior endoscopic treatment for esophageal adenocarcinoma of BE associated neoplasia;

2. Signs of local or distant metastasis on EUS (EUS is obligatory);

3. Signs of distant metastasis on CT-scan of thorax and/or abdomen (optional for mucosal lesions);

4. Any of the following findings in any of the ER specimens:

A. G3 or G4 tumor differentiation;

B. Lymphatic invasion;

C. Infiltration into the submucosa >500ÂµÂµm;

D. A positive deeper resection margin.

5. Endoscopic signs of esophageal varices;

6. Esophageal stenosis not allowing passage of a therapeutic endoscope with an ER-cap;

7. Prior esophageal surgery (except fundoplication).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2008
Enrollment:	24
Type:	Actual

Ethics review

Positive opinion

Date:	05-10-2010
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	NL2433
NTR-old	NTR2542
Other	METC AMC : 09/109
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A