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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29052

Bron
NTR

Aandoening

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.

Ondersteuning

Primaire sponsor: -
Overige ondersteuning: BARRX Medical, Sunnyvale (CA), USA

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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.

Onderzoeksopzet

1. 0 months: Combined ER and RFA procedure;

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

3. 12 months: Assessment of primary endpoints.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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 <500ÂµmÂ;

6. Written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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 >500ÂµmÂ;

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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-12-2008
Aantal proefpersonen:	24
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	05-10-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2433
NTR-old	NTR2542
Ander register	METC AMC : 09/109
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A