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.

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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...

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

Samenvatting

ID

NL-OMON27256

Bron
NTR

Verkorte titel
EURO-I

Aandoening

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

Ondersteuning

Primaire sponsor: Academic Medical Center (AMC), Department of Hepato- and Gastroenterology
Overige ondersteuning: BÂRRX Medical Inc. Sunnyvale, California, US

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-07-2006
Aantal proefpersonen:	30
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	05-09-2008
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	NL1374
NTR-old	NTR1434
Ander register	: MEC 06/189
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A