Self-sizing Radiofrequency Ablation balloon for eradication of Barrett's esophagus: a randomized trial comparing three different treatment regimens

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The percentage of endoscopic resolution of Barrett’s esophagus at 3 months is non-inferior with two simple protocol versus the standard protocol.

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

Samenvatting

ID

NL-OMON24632

Bron
NTR

Aandoening

Barrett's esophagus, Barrett's neoplasia, Barrett's dysplasia, Radiofrequency ablation, Intestinal metaplasia

Ondersteuning

Primaire sponsor: KU Gasthuisberg Leuven, Belgium
Overige ondersteuning: Covidien GI Solutions

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary outcome:
Percentage of endoscopically visual surface regression of BE epithelium at 3 months, as scored
by two independent endoscopists blinded to the treatment regimen.

Toelichting onderzoek

Achtergrond van het onderzoek

In this trial, three regimens for circumferential

radiofrequency ablation treatment with the RFA self-sizing

balloonWill be compared The first regimen is the standardly

used regimen (1x-clean-1x) The two simple regimens are

the simplified protocol with 2x-ablation-no clean and the

simplified protocol with 1x ablation-no clean.

Doel van het onderzoek

The percentage of endoscopic resolution of Barrett’s esophagus at 3 months is non-inferior with two simple protocol versus the standard protocol.

Onderzoeksopzet

1. At follow-up endscopy at 3 months after the circumferential RFA treatment the primary endpoint will be scored

2. During and in the interval from directly after the circumferential RFA procedure until follow-up endoscopy after 3 months, the secondary endpoints are scored

Onderzoeksproduct en/of interventie

Circumferential radiofrequency ablation of Barrett's
esophagus with the Self-sizing RFA balloon.

Inspection of the Barrett’s segment and randomization

The esophagus is evaluated using white light high-resolution endoscopy (WLE) and narrow band imaging (NBI). The extent of columnar lined esophagus is documented according to the Prague C&M classification15 and by taking still images with WLE+NBI at 1 cm intervals. In the absence of visible abnormalities and no severe stenosis, patients are subsequently randomized to circumferential ablation with the Self Sizing RFA balloon using the simplified or the standard ablation regiment.

Patients will be blinded for the administered treatment regimen.

Standard ablation regimen
After mapping and randomization, the Barrett's segment is flushed with the mucolytic agent acetylcysteine (1%) followed by flushing with tap water. The Self Sizing RFA balloon (GI Solutions Covidien, Sunnyvale, CA) is then introduced and positioned at the desired treatment zone. The device is inflated, and the electrode unfurls until the electrode contacts the esophageal wall. Under visual control the BE is ablated (12 J/cm2 at 300 Watt) working proximal to distal using visual repositioning. A small overlap (i.e. <1cm) between ablation zones is allowed. After the first ablation pass, the endoscope is removed followed by removal of the ablation catheter. The coagulum is cleaned off the balloon catheter. The endoscope is reintroduced to irrigate and suction the ablation zone. A distal attachment cap may be attached to the tip of the endoscope to gently wipe of the coagulum from the ablated segment. After irrigating and suctioning the debris away as much as possible, the Self Sizing RFA RCT November 2014 vs 1 Page 10 van 16 ablation zone is cleaned by forcefully flushing water through a spraying catheter. The stomach is emptied and deflated, the endoscope is removed and the ablation catheter is reintroduced to repeat the ablation. After this second ablation no additional cleaning of the ablation zone is required. First, the endoscope is removed, followed by careful removal of the ablation catheter.

Simplified ablation regimens:
In the first simplified ablation regimen flushing with the mucolytic agent acetylcysteine (1%) is not performed, but the esophageal wall will cleaned with water through the waterjet channel of the endoscope. After the first ablation (12 J/cm2 at 300W), immediately a second ablation is performed of the same zone without a cleaning step. After

deflation, the balloon is advanced distally to ablate subsequent zones with a double ablation in an identical way.

In the second simplified ablation regimen flushing with the mucolytic agent acetylcysteine (1%) is not performed, but the esophageal wall will cleaned with water through the waterjet channel of the endoscope. There is only one ablation instead of two.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients aged 18-85 years, with biopsy proven LGD, HGD or EC in a BE after local expert pathology review.

2. Scheduled circumferential ablation for BE with flat LGD, HGD, or for BE after prior endoscopic
resection (ER) for lesions containing HGD or EC (<2 cm and <50% of the circumference).

3. Pretreatment biopsies and/or ER specimens reviewed by a local expert pathologist.

4. Written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients with a BE segment < 2cm or >15 cm prior to ER.

2. Any prior endoscopic ablation treatment.

3. Significant esophageal stenosis prior to initial treatment, preventing passage of a therapeutic
endoscope OR any prior endoscopic dilatation for esophageal stenosis.

4. Presence of esophageal varices.

5. Anti-coagulant therapy (apart from aspirin or NSAID) that cannot be discontinued prior to ER
or RFA, OR uncorrectable hemostatic disorders.

6. In case of prior ER: patients with ER of multiple lesions in a single ER session are not eligible, if
one of the resections measures more than the aforementioned size criteria, OR if resections of different lesions are not separated by a free circumferential segment of at least 1 cm.

7. In case of prior ER: a specimen showing carcinoma with positive vertical resection margins, deep submucosal invasion (>T1sm1), poorly or undifferentiated cancer (G3 or G4), or lymphatic/vascular invasion.

8. In case of prior ER: invasive cancer in any of the biopsies obtained at high-resolution endoscopy after ER.

9. An interval > 6 months between the last high-resolution endoscopy with biopsies and RFA.

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

11. Patients unable to give informed consent.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-09-2015
Aantal proefpersonen:	108
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	18-05-2015
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	NL5059
NTR-old	NTR5191
Ander register	NL51663.018.14 CCMO : 2014_380 METC AMC

Resultaten

Samenvatting resultaten
In preparation