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.

Gepubliceerd: 12-06-2008 Laatst bijgewerkt: 13-12-2022

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

Samenvatting

ID

NL-OMON21764

Bron
NTR

Verkorte titel
AMC-IV

Aandoening

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.

Ondersteuning

Primaire sponsor: BÂRRX Medical Inc.
540 Oakmead Parkway
Sunnyvale, CA 94085
Overige ondersteuning: BÂRRX Medical Inc.
540 Oakmead Parkway
Sunnyvale, CA 94085

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Onderzoeksopzet

- 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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2006
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	12-06-2008
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	NL1290
NTR-old	NTR1337
Ander register	: B-206
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A