Efficacy and safety of focal cryoballoon ablation for patients with dysplastic Barrett's esophagus

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Focal cryoballoon ablation is an effective and safe treatment modality for patients with dysplastic Barrett's esophagus.

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

Samenvatting

ID

NL-OMON25207

Bron
NTR

Verkorte titel
EURO-COLDPLAY

Aandoening

Barrett's esophagus
Barrett slokdarm

Ondersteuning

Primaire sponsor: St. Antonius Hospital, Nieuwegein
Overige ondersteuning: Pentax

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Efficacy, defined as:
- CE-IM; the percentage of patients with complete eradication of all Barrett’s epithelium on endoscopy AND CE-IM in all biopsies obtained at the first follow-up endoscopy after the maximum of 5 treatment sessions (and escape treatment(s) if necessary).
- CE-D; the percentage of patients with CE-D in all biopsies obtained at the first follow-up endoscopy after the maximum of 5 treatment sessions (and escape treatment(s) if necessary).

Toelichting onderzoek

Achtergrond van het onderzoek

Evaluation of the efficacy and safety of the C2 Cryoballoon Focal Ablation system.

Doel van het onderzoek

Focal cryoballoon ablation is an effective and safe treatment modality for patients with dysplastic Barrett's esophagus.

Onderzoeksopzet

Baseline (first treatment endoscopy), follow-up endoscopies at a 3 month interval, last treatment endoscopy.

Onderzoeksproduct en/of interventie

CryoBalloon™ Focal Ablation System (CbFAS)

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Indicated for ablation therapy of Barrett’s epithelium, determined by:

o Histopathologically-confirmed LGD or HGD in flat-type BE with four quadrant biopsies of every 2cm of the BE segment in the last 6 months, or

o Residual flat BE (with or without dysplasia) after endoscopic resection of a focal lesion (by means of EMR or ESD) of non-flat BE, at least 6 weeks prior to enrolling the patient to this study. The histopathologic evaluation of the resected specimen should indicate endoscopic treatment (i.e., no more than only superficial submucosal invasion (≤T1sm1/<500 microns), absence of lymphovascular invasion, not poorly differentiated, free deep (vertical) resection margins).

NB: In case of performed endoscopic resection, the absence of residual cancer in the remaining Barrett’s epithelium should be confirmed with random biopsies (these biopsies might be taken during the same endoscopy, but a maximum interval of 6 months is allowed between these biopsies and study inclusion).

- Ablation naïve (no previous ablation therapy of the esophagus)

- Prague Classification ≤C2 / ≤M5 (including BE tongues, excluding small BE islands, in case of endoscopic resection Prague Classification AFTER endoscopic resection)

- Older than 18 years of age at time of consent

- Operable per institution’s standards

- Informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Esophageal stenosis preventing advancement of a therapeutic endoscope

- Prior endoscopic resection (EMR or ESD) >2cm in length AND/OR >50% of the esophageal circumference

- Prior distal oesophagectomy

- Active oesophagitis grade B or higher (patients can be included after appropriate treatment of reflux oesophagitis)

- History of oesophageal varices

- Achalasia

- Severe medical comorbidities precluding endoscopy

- Uncontrolled coagulopathy

- Pregnant or planning to become pregnant during period of study participation

- Life expectancy ≤2 years, as judged by the site investigator

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 gestart
(Verwachte) startdatum:	01-10-2018

Aantal proefpersonen:	107
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	06-09-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50590
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7253
NTR-old	NTR7460
CCMO	NL64555.100.18
OMON	NL-OMON50590

Resultaten