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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25207

Source
NTR

Brief title
EURO-COLDPLAY

Health condition

Barrett's esophagus
Barrett slokdarm

Sponsors and support

Primary sponsor: St. Antonius Hospital, Nieuwegein
Source(s) of monetary or material Support: Pentax

Intervention

Outcome measures

Primary outcome

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).

Secondary outcome

o Safety: Incidence of FCBAS related serious adverse events

o CE-IM stratified by baseline stratum (treatment naïve, post-endoscopic resection) and baseline dysplasia grade (LGD, HGD, EAC).

o CE-D stratified by baseline stratum (treatment naïve, post-endoscopic resection) and baseline dysplasia grade (LGD, HGD, EAC).

o Number of CBA treatments required to achieve CE-IM and/or CE-D.

o Percentage of patients requiring escape treatment (EMR, APC) during study participation in order to achieve CE-IM and/or CE-D.

o Percentage of patients with progression to LGD, HGD or cancer at first follow-up endoscopy.

o Incidence of all (non-treatment related) serious adverse events

o Incidence of treatment-related adverse events

o Post-procedural pain in the area of CBA treatment scored on a 0-10 point numeric rating scale (NRS) for pain

o Post-procedural dysphagia on a validated scale from 0-4

o Usage of analgesics after treatment

o Technical success, defined as the percentage of treatment sessions considered complete, which is defined as treatment of all visible BE and the EGJ circumferentially.

o The percentage of treatment sessions with device malfunctions (device malfunction is defined as problems with the device or a part of the device that require (partially) device replacement.

Study description

Background summary

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

Study objective

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

Study design

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

Intervention

CryoBalloon™ Focal Ablation System (CbFAS)

Contacts

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Eligibility criteria

Inclusion criteria

- 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

Exclusion criteria

- 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

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2018
Enrollment:	107
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	06-09-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50590
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results