Clinical trial to evaluate safety and efficacy of the C2 CryoBalloon 180° Ablation System for the treatment of dysplastic Barrett*s esophagus: CBAS180 de-escalation study

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Evaluate the efficacy and safety of the C2 CryoBalloon 180° Ablatie Systeem (CBAS180) at decremental doses for the treatment of dysplastic Barrett*s epithelium.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON52660

Source
ToetsingOnline

Brief title
CBAS180 de-escalation study

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
Barrett's esophagus, Barrett's neoplasia

Research involving
Human

Sponsors and support

Primary sponsor: Pentax Medical
Source(s) of monetary or material Support: Pentax Medical

Intervention

Keyword: Ablation therapy, Barrett's esophagus, Cryoballoon ablation, Cryotherapy

Outcome measures

Primary outcome

1) Efficacy defined as the median BE surface regression percentage after 1 circumferential treatment session, as evaluated by the EGD-Adjudication Committee and confirmed by histological evidence of eradication of BE.

2) Safety defined as the incidence of dose-related serious adverse events.

Secondary outcome

1) Feasibility (technical success) defined as the percentage of patients in whom all BE could be treated as intended by the treating endoscopist.

2) Post-procedure pain in the area of the cryoablation treatment (0-10 NRS), described as the median pain scores directly, 1, 7 and 30 days after treatment.

3) Post-procedure dysphagia (scored on a 0-4 dysphagia score), described as the median dysphagia scores directly, 1, 7 and 30 days after treatment.

4) Incidence of all serious and non-serious AEs up to 30 days post-treatment.

5) Median BE surface regression percentage after 1 circumferential treatment session as assessed by the treating endoscopist.

Study description

Background summary

Cryoballoon ablation is a relatively new ablation technique for the treatment of dysplastisch Barrett's esophagus (BE). Previous studies with this technique have shown that treatment is safe and effective. When compared to other ablation techniques, cryoballon ablation has several potential advantages, including less pain and less complications such as stricture formation after treatment. Recently, a cryoballoon ablation system has become available which enables treatment of larger esophageal surfaces. Although a recent clinical study with this new device has shown promising results, the lowest possible dose that optimally balances safety and efficacy is still unknown.

Study objective

Evaluate the efficacy and safety of the C2 CryoBalloon 180° Ablatie Systeem (CBAS180) at decremental doses for the treatment of dysplastic Barrett*s epithelium.

Study design

Multicenter, prospective, non-randomized, intervention study.

Intervention

Circumferential ablation of 3cm of length of Barrett*s epithelium using the CBAS180 at decremental dosages during an upper endoscopy.

Study burden and risks

The nature and extent of the burden and risks associated with study participation are minimal. Preliminary results of the CBAS180 have shown good efficacy and safety. Since we only slightly lower the doses for the current study in comparison to previous studies, we do not have concerns regarding efficacy or safety. We do not anticipate that patients will require more treatment sessions or be exposed to a higher complication risk compared to current standard of care, radiofrequency ablation. On the contrary, cryoablation is thought to preserve the extracellular matrix, which may result in less pain and lower stricture rates and therefore better patient tolerability.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1) Flat type BE esophagus, with an indication for ablation therapy, defined as:
a) Diagnosis of LGD or HGD in BE (confirmed by BE expert pathologist) or;
b) Residual BE with any grade of dysplasia after endoscopic resection (by means of EMR or ESD) to treat non-flat BE, >=6 weeks prior to enrolling the patient to this study. The ER pathology should indicate endoscopic treatment (i.e. only mucosal invasion or limited submucosal invasion (sm1), no lymphovascular infiltration, free vertical resection margins and not poorly differentiated).
2) Prague Classification Score of C<=3 and M>=1.
3) Patients should be ablation-naïve, meaning they have not undergone any previous endoscopic ablation therapy of the esophagus.
4) Older than 18 years of age at time of consent.
5) Fit for endoscopic therapy per institution*s standards.
6) Provides written informed consent on the IRB-approved informed consent form.
7) Willing and able to comply with follow-up requirements.

Exclusion criteria

1) Esophageal stenosis preventing advancement of a therapeutic endoscope.

2) Any endoscopically visualized lesion such as ulcers, masses or nodules. Neoplastic nodules must first be treated with ER >=6 weeks prior to planned treatment under this protocol.
3) Prior ER of >2cm in length and/or >50% of the esophageal lumen circumference.
4) History of locally advanced (>sm1) esophageal cancer.
5) History of esophageal varices.
6) Prior distal esophagectomy.
7) Active esophagitis LA grade B or higher.
8) Severe medical comorbidities precluding endoscopy.
9) Uncontrolled coagulopathy.
10) Pregnant or planning to become pregnant during period of study.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-01-2023
Enrollment:	122
Type:	Actual

Medical products/devices used

Generic name:	CryoBalloon 180° Ablation System
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	13-12-2022

Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	27-03-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-09-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	22-01-2025
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT05740189
CCMO	NL73252.000.22