Multicenter European prospective study on the efficacy and safety of the Focal C2 CryoBalloon Ablation System in patients with Barrett*s Esophagus-related neoplasia

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To evaluate the efficacy and safety of the Focal C2 CryoBalloon* Ablation System (FCBAS) for the treatment of Barrett*s epithelium.

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

Summary

ID

NL-OMON50590

Source
ToetsingOnline

Brief title
Euro-Coldplay

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms malignant and unspecified

Synonym
Barrett's esophagus, Barrett's neoplasia

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W,C2 Therapeutics, Pentax Medical

Intervention

Keyword: Ablation therapy, Barrett's esophagus, Cryoablation, Focal Cryoballoon Ablation

Outcome measures

Primary outcome

The primary endpoint is efficacy, defined as:

- Complete eradication of intestinal metaplasia (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 treatments if necessary).

- Complete eradication of dysplasia (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 if necessary).

Secondary outcome

- Safety: Incidence of FCBAS related serious adverse events

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

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

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

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

- Percentage of patients with progression to LGD, HGD or cancer at first follow-up endoscopy.
- Incidence of all (non-treatment related) serious adverse events
- Incidence of treatment-related adverse events: for the definition of treatment-related adverse events and classification please see section 8.2.1 of the protocol.
- Post-procedural pain in the area of CBA treatment scored on a 0-10 point numeric rating scale (NRS) for pain, registered daily during 2 weeks in a patient diary (electronic or paper, depending on the wishes of the patient).
- Post-procedural dysphagia on a validated scale from 0-4, registered daily during 2 weeks in a patient diary (electronic or paper, depending on the wishes of the patient).
- Usage of analgesics after treatment: registered daily during 2 weeks in a patient diary (electronic or paper, depending on the wishes of the patient).
- Technical success, defined as the percentage of treatment sessions considered complete, which is defined as treatment of all visible BE as intended by the endoscopist.
- 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.
- Satisfaction score as given by the endoscopist directly after the treatment session (range 1-10, with 1 being the lowest score, 10 the highest).
- Durability of complete eradication of intestinal metaplasia and dysplasia during follow-up: defined as the recurrence of intestinal metaplasia or

dysplasia during follow-up.

Study description

Background summary

Cryotherapy has been used for years to eradicate flat dysplastic Barrett*s esophagus (BE). It preserves the extracellular matrix and may be better tolerated and might result in lower stricture rates when compared to other ablation techniques, without compromising on efficacy. C2 CryoBalloon Ablation (CBA) is a relatively new method for application of cryotherapy. Previous studies with limited number of patients have shown promising results.

Study objective

To evaluate the efficacy and safety of the Focal C2 CryoBalloon* Ablation System (FCBAS) for the treatment of Barrett*s epithelium.

Study design

European, multicenter, prospective, single arm, non-randomized intervention study

Intervention

Focal CBA therapy until complete eradication of intestinal metaplasia (CE-IM) is established, with a maximum of 5 subsequent CBA treatment sessions per patient. Escape treatment may be performed: for lesions <5mm a maximum of 2 argon plasma coagulation (APC) treatment sessions, and for lesions of >5mm single endoscopic mucosal resection (EMR).

Study burden and risks

The nature and extent of the burden and risks associated with study participation are minimal. There are multiple treatment sessions included in the study protocol, but these replace treatment sessions that patients would have received had they been treated according to site standard of care. FCBA has been shown to be effective and safe in previous studies and therefore it is not anticipated that patients will require more treatment sessions or be exposed to a higher complication risk. On the contrary, CBA is thought to preserve the extracellular matrix, which may result in less pain and lower stricture rates and therefore better patient tolerability. Extra activities for patients include: 1) filling out a short questionnaire on symptoms, daily for 2

weeks after every endoscopic treatment session; 2) Phone contact 7 days after every treatment session to evaluate symptoms and adverse events.

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. 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).
2. Ablation naïve (no previous ablation therapy of the esophagus)
3. Prague Classification <=C2 / <=M5 (including BE tongues, excluding small BE islands, in case of endoscopic resection the Prague Classification AFTER endoscopic resection)
4. Older than 18 years of age at time of consent
5. Operable per institution*s standards
6. Informed consent

Exclusion criteria

1. Esophageal stenosis preventing advancement of a therapeutic endoscope
2. Prior endoscopic resection (EMR or ESD) >2cm in length AND/OR >50% of the esophageal circumference
3. Prior distal oesophagectomy
4. Active oesophagitis grade B or higher (patients can be included after appropriate treatment of reflux oesophagitis)
5. History of oesophageal varices
6. Achalasia
7. Severe medical comorbidities precluding endoscopy
8. Uncontrolled coagulopathy
9. Pregnant or planning to become pregnant during period of study participation
10. Life expectancy <=2 years, as judged by the site investigator

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-04-2019
Enrollment:	42
Type:	Actual

Medical products/devices used

Generic name:	Focal Cryoballoon Ablation System
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	09-10-2018
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	25-02-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-02-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	17-06-2020
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

ID: 25207
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
Other	NL 7253
CCMO	NL64555.100.18
OMON	NL-OMON25207