CLINICAL TRIAL TO EVALUATE SAFETY AND DOSE RESPONSE USING THE C2 CRYOBALLOON SWIPE ABLATION SYSTEM FOR THE TREATMENT OF BARRETT*S ESOPHAGUS

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The objective of this study is to determine the safety and efficacy of the dose required for eradication of LGD or HGD in BE, or residual BE after endoscopic removal of early cancer (*therapeutic dose*), using the C2 CryoBalloon Swipe System.

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

Summary

ID

NL-OMON43223

Source
ToetsingOnline

Brief title
Swipe dose response study

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
Barrett's esophagus, esophageal cancer

Research involving
Human

Sponsors and support

Primary sponsor: C2Therapeutics, Marcia Wachna
Source(s) of monetary or material Support: C2 Therapeutics;Inc.

Intervention

Keyword: Barrett's esophagus, Cryoablation, Cryotherapy, Esophageal neoplasms

Outcome measures

Primary outcome

1. Safety: will be evaluated by the incidence of Dose-related SAEs.

Dose-related SAEs include pain in the treatment area greater than 6 (on VAS) on 24 hours AND 7 days post-treatment; symptomatic stricture requiring an additional EGD plus endoscopic dilation before first follow-up EGD; symptomatic stricture requiring endoscopic dilation at follow-up EGD; or any stricture (symptomatic or asymptomatic) preventing passage of the diagnostic endoscope at follow-up EGD. Any other serious adverse events within 30 days after treatment will also be evaluated by DSMB for relationship to the dose and severity.

2. Dose response (efficacy), which is defined as eradication percentage of BE confirmed by histological evidence of eradication of BE, after two-step circumferential treatment with the therapeutic dose. The eradication percentage will be assessed by the EGD-Adjudication Committee, consisting of at least two (2) physicians specialized in gastroenterology, by comparing pre-treatment and follow-up digital images of the ablated areas in a systematic and standardized manner.

Secondary outcome

1. Incidence of all serious and non-serious adverse events up to 30 days

post-treatment

2. Post-procedure pain in the area of the cryoablation treatment (scored on a 1

to 10- point VAS),

3. Efficacy, defined as the regression percentage at the first follow-up

endoscopy, after 1 treatment covering 50% of circumference with the therapeutic

dose

4. Efficacy of treatment with CryoBalloon Swipe Ablation System, defined as the

number of patients with a regression percentage of 80% or higher after

hemicircumferential treatment

Study description

Background summary

Barrett's Esophagus (BE) is a premalignant lesion which can lead to esophageal adenocarcinoma. This particular cancer is one of the most rapidly increasing and deadliest cancers in the western world. Patients with BE are up to 40 times more at risk of adenocarcinoma than individuals without BE. Once diagnosed with BE, a patient enters a life-long surveillance program in which upper endoscopies with biopsy are performed to survey the progression of the Barrett's tissue to cancer. For more than 20 years, many technologies have been evaluated for ablation of BE. Elimination of BE and restoration of squamous esophageal lining has been demonstrated through ablation; however, no ablation technology currently provides the necessary attributes for wide-spread adoption. The CryoBalloon Ablation System (System) is designed to address many of the limitations of current ablation technologies. The simplicity of the System allows for many potential benefits to the patient, the physician, and hospital. Some of the benefits may include a shorter and safer procedure, an easier deployment minimizing the need for anesthesiology, and smaller inventory requirements and no capital equipment improving capital resource utilization. Additionally, patients may experience less pain after cryoablation compared with other ablation techniques.
First, the System has undergone acute and chronic animal testing. The testing was conducted to study the safety, deliverability and performance

characteristics of the System. The studies were conducted for the evaluation of the device in a normal pig esophagus at dimensions very similar to a human esophagus. General follow-up time frames were either 4 days or 28 days. Hereafter, three human trial has been performed with the Focal cryoablation system which evaluated the safety of the this Focal system with several doses, the device perfomance status, and the efficacy. The studies showed safe treatment and high efficacy for cryoablation, with 100% eradication of Barretts epithelium in the patients treated with the maximal dose (10 sec). Currently, several trials are enrolling patients to study efficacy of the System even better. Anyhow, this Focal system is only able to treat relatively little Barrett*s Tissue. When ablating larger areas with this focal device an important risk will exist that certain areas won*t be treated or just overtreated and, additionally, it be a very time-consuming procedure. Therefore the Swipe Sytem was recently introduced by C2 Therapeutics. This device ablates a larger area in one ablation, thereby enabling the ablation of larger BE tissue. This system was investigated in animal trials and in one human trial, and it was judged to be safe. Now we want to study the efficacy of the device in different doses, in order to find the efficacy at the optimal dose.

Study objective

The objective of this study is to determine the safety and efficacy of the dose required for eradication of LGD or HGD in BE, or residual BE after endoscopic removal of early cancer (*therapeutic dose*), using the C2 CryoBalloon Swipe System.

Study design

Prospective, mulit-center, single-arm and non-randomized clinical trial

Intervention

Endoscopic balloon based cryoablation. The System has three (3) main components: a delivery catheter with a spray-hole covered by a balloon probe, a single-use disposable handle and a cartridge containing the cryogenic fluid. The catheter can be inserted into the working channel of a therapeutic endoscope. Once deployed, the balloon is simultaneaously inflated and cooled with cryogenic fluid from the cartridge. The BE cells of the esophagus will be ablated if they come into contact with the cooled balloon. In the Swipe system, the spray hole of the catheter will automatically be pulled back during ablation. In this way, an area of 3 cm in length covering about 25% of the circumference (depending on the size of the esophagus) will be freezed. The dosing will be expressed in the speed (in mm/sec) whereby the catheter will be pulled back during the ablation (lower speeds means a higher dose). In this way, patients will be treated for 50% of their circumference (with 1-3

ablations necessary depending on the size of the esophagus) over a length of 3 cm.
Patients in phase I will undergo one single treatment, to treat 50% of esophageal circumference. Patients in phase II (after the therapeutic dose will be defined) will undergo a second treatment with the Swipe device to treat the contrary 50% of esophageal circumference. This second treatment will be performed 2 months after the first treatment.

Study burden and risks

Patients will undergo 2 to 3 gastroscopies in this study, which will both be performed for regular medical reasons anyway. The difference compared to regular treatment is that during the first endoscopy (and the second, in case of three endoscopies) patients will be treated with the swipe cryoablation system instead of regular RFA treatment. During follow-up endoscopy a thorough inspection of the esophagus and biopsies will be performed in accordance with the standards of care. If necessary, additional treatment will be performed with RFA. Patients need to adhere to a soft diet during 2 days after the cryoablation. Furthermore patients will be contacted by telephone 2 and 7 days after the cryoablation. Finally, patients may experience temporary limited pain, which can be treated with paracetamol.

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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. Patients with flat-type (Paris type 0-IIb) BE esophagus, with an indication for ablation therapy, meaning:
* Diagnosis of Low-grade dysplasia (LGD) or high-grade dysplasia (HGD) in BE (confirmed by baseline histopathological analysis), OR
* 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, no lymphovascular infiltration, free vertical resection margins and not poorly differentiated)
2. Prague Classification Score C*3
3. Patients should be ablative-naïve, meaning they did not undergo any previous ablation therapy of the esophagus
4. Older than 18 years of age at time of consent
5. Operable 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 or stricture 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 >2cm in length and >50% of the esophageal lumen circumference
4. History of esophageal cancer (>T1a)
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
11. Patient refuses or is unable to provide written informed consent
12. Participation in another study with investigational drug or device within the 30 days preceding or during the present study, interfering with participation in this trial
13. General poor health, multiple co-morbidities placing the patient at risk or otherwise unsuitable for trial participation

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-03-2017
Enrollment:	18
Type:	Actual

Medical products/devices used

Generic name:	C2 Therapeutics' Cryoballoon Swipe Ablation System (System)
Registration:	No

Ethics review

Approved WMO Date:	13-02-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-10-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
CCMO	NL59918.018.16
Other	Volgt