CLINICAL STUDY TO EVALUATE THE COLDPLAY CRYOBALLOON FULL AND SWIPE ABLATION SYSTEMS FOR THE ABLATION OF HUMAN ESOPHAGEAL EPITHELIUM IN PATIENTS UNDERGOING ESOPHAGECTOMY

Published: 25-08-2015
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The primary objective of this study is to evaluate the safety and performance of the CryoBalloon Ablation Systems (Full and Swipe) for the ablation of human esophageal epithelium.

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

Summary

ID

NL-OMON43660

Source
ToetsingOnline

Brief title
ECCAS

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
esophageal cancer, esophageal neoplasm

Research involving

Human

Sponsors and support

Primary sponsor: C2 Therapeutics
Source(s) of monetary or material Support: C2 Therapeutics

Intervention

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

Outcome measures

Primary outcome

Safety of the CryoBalloon Ablation Systems (Full and Swipe) will be evaluated by the incidence of serious, device-related events.

Device performance will be evaluated by ease of deployment (length of time), scope compatibility, application of cryogenic fluid, device malfunction (eg., unresponsive trigger, failure to diffuse nitrous oxide, etc.).

Secondary outcome

Treatment effect of the Coldplay CryoBalloon Full and Swipe Ablation Systems will be evaluated by depth and uniformity of ablation effect in the esophagus.

An esophagectomy will be performed immediately following the ablation procedure; histopathological analysis of surgically-resected specimens will be done.

Study description

Background summary

Esophageal canceris the sixth leading cause of cancer death in the world . Patients with Barrett*s esophagus have an increased risk for developing esophageal adenocarcinoma. Malignant degeneration is believed to occur in a

stepwise fashion from nondysplastic intestinal metaplasia, to low-grade and then high-grade dysplasia. Endoscopic surveillance to evaluate the progression to dysplasia has become the standard of practice in the management of patients with Barrett*s Esophagus.

The goal of therapy is the elimination of Barrett*s Esophagus (BE) and restoration of squamous esophageal mucosal lining. Endoscopic treatments for BE include Endoscopic Mucosal Resection (EMR) and/or endoscopic ablative techniques based on cryogenic, thermal non-contact (such as argon plasma coagulation - APC) or thermal contact (radiofrequency ablation - RFA) technology. For visible lesions in BE, EMR is performed, while for high-grade dysplasia in flat BE, ablative treatment is carried out. Moreover, a recent study showed that ablation of low-grade dysplasia reduced the risk of progression to high-grade or adenocarcinoma by 25%.

An important drawback of current available ablation techniques (RFA, APC) is that they do not provide the necessary attributes for widespread adoption, because of side effects, lack of predictability as to depth of ablation (as in APC), length of procedure time, or cost (eg., inventory requirements, the need for capital equipment).

C2 Therapeutics, Inc. (Redwood City, CA, USA) develops balloon-based cryotherapy devices for the removal of unwanted tissue in endoscopic procedures. The Coldplay CryoBalloonTM Ablation System provides controlled cryotherapy ablation for the treatment of BE. Deployed through the working channel of an endoscope, the Balloon is simultaneously inflated and cooled with an inert cryogen (nitrous oxide) delivered from the Handle that ablates the BE cells upon contact with the esophagus. After ablation, the Balloon is repositioned for additional ablation or withdrawn. The System may allow for potential benefits to the patient, the physician, and hospital, including a shorter and safer procedure, an easier deployment reducing the need for anaesthesiology, and smaller device inventory and no capital equipment requirement

C2 Therapeutics has developed both a Swipe design (similar to the previous Focal version) and Full design of the System. The Swipe design ablates an area of approximately 90 degrees of the esophageal circumference (about the size of a 20-cent Euro coin) and approximately 3cm in length. The Full System is designed to apply refrigerant in a 360-degree pattern such that the entire circumference of a specific length (approximately 3cm) of the esophagus is treated with each application. The Swipe System and Full System are available for investigational use only in the European Union (CE-mark is pending).

The Swipe System and Full System that are the focus of this study are the second generation designs. The first generations of the systems were evaluated in clinical studies:

1. The first generation Full System was evaluated in a prospective clinical study that enrolled patients scheduled for esophagectomy for esophageal cancer who agreed to have the cryoablation performed prior to their surgery. A total of 21 ablations were performed in 13 patients. There were no adverse events. Histological analysis confirmed that none of the ablation sites penetrated the esophageal wall, and viable vasculature was present to the depth of the

submucosa in half of the specimens. Depth of injury (necrosis with or without inflammation and edema) extended to the submucosa in ten of 21 of the ablation sites; necrosis extended to the muscularis mucosa in one (1) patient.
2. The first generation Focal System was first evaluated in an extension to the pre-esophagectomy study using the Full System. The Focal System was used to treat four (4) patients. Subsequently, a prospective, multi-centre clinical study enrolling 39 patients requiring treatment for Barrett*s Esophagus was conducted. A total of 56 ablations were successfully performed. There were no serious adverse events, and five (5) non-serious adverse events of mucosal laceration that did not require treatment. Full squamous regeneration was seen in 47 (85%) treated areas. These studies confirmed that ablation of unwanted tissue in the esophagus using the CryoBalloonTM Focal Ablation System is feasible and safe, and results in squamous regeneration in the majority of patients.
While these studies confirmed the safety and performance of the CryoBalloonTM Ablation Systems, the modified Full System and Swipe System have been developed to improve the uniformity of refrigerant delivery and to increase the length of esophageal tissue that can be treated in one application.

Study objective

The primary objective of this study is to evaluate the safety and performance of the CryoBalloon Ablation Systems (Full and Swipe) for the ablation of human esophageal epithelium.

Study design

Prospective, non-randomised, single-centre single-arm study

Intervention

Treatment with the Coldplay CryoBalloon Ablation Systems (Full and/or Swipe)

Study burden and risks

Complications specific to the CryoBalloon Full System include perforation or laceration to the esophageal wall.

There is no direct benefit of study participation. However, other patients may benefit in the future from what is learned as a result of this study.

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. 1 or 2 areas of 3 cm non-ulcerated columnar-lined esophagus or squamous- lined tissue suitable for ablation. Each ablation zone should be at least 1 cm from the tumor and a minimum of 3 cm in length. Sequential ablation zones must be a minimum of 1 cm apart.
2. Patient is older than 18 years of age at the time of consent.
3. Patient requires a clinically-necessary esophagectomy for esophageal cancer.
4. Patient has provided written informed consent using the Informed Consent Form (ICF) approved by the Institution*s reviewing Medical Ethics Committee (MEC).

Exclusion criteria

1. Patient refuses or is unable to provide written informed consent.
2. Patient has esophageal narrowing limiting access to the intended site of ablation.

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):	16-10-2015
Enrollment:	5
Type:	Actual

Medical products/devices used

Generic name:	Coldplay CryoBalloon Full Ablation System and Coldplay CryoBalloon Swipe Ablation System
Registration:	No

Ethics review

Approved WMO Date:	25-08-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-12-2015
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

ID: 29603
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL53312.018.15
OMON	NL-OMON29603