Evaluation of Balloon-based Cryoablation of Human Esophageal Epithelium

Published: 03-01-2011
Last updated: 04-05-2024

This is a feasibility study of the System to assess safety and performance in patients scheduled to undergo esophagectomy.

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

Summary

ID

NL-OMON36325

Source
ToetsingOnline

Brief title
EBCA

Condition

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

Synonym
esophageal cancer, esophageal neoplasm

Research involving
Human

Sponsors and support

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

Intervention

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

Outcome measures

Primary outcome

Histological aspect of tissue after balloon based cryoabalation:

(1) the percentage of mucosa ablated (**Ablation** is defined as any sign of

irreversible injury (necrosis)).

(2) the anatomic depth of injury.

(3) a detailed description of the type of injury at each depth of the

esophageal wall.

Secondary outcome

(1) Deployment ease/endoscope compatibility.

(2) Flow of the cryogenic fluid.

(3) Balloon pressure.

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 endoscopy 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 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
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. The experience to date supports the need for further investigation in a human clinical trial.

Study objective

This is a feasibility study of the System to assess safety and performance in patients scheduled to undergo esophagectomy.

Study design

Prospective, multi-center, single-arm and non-randomized.

Intervention

Endoscopic balloon based cryoablation.
The System has two main components: the delivery catheter with balloon probe and a disposable handle containing the cryogenic fluid. Deployed through the working channel of an endoscope, the operation of the System is very similar to the deployment of dilatation balloons. Once deployed, the balloon is simultaneously inflated and cooled with cryogenic fluid delivered from the handle. BE cells are ablated as the balloon comes into contact with the esophagus for less than 15 seconds. After ablation, the System is repositioned for additional ablation or withdrawn.

Study burden and risks

If patients participate, their regular endoscopy will be prolonged with 15 minutes and patients need to adhere to a soft diet during 2 days after the cryoablation (unless the esophagectomy will follow directly upon the endoscopic treatment). Furthermore patients will be contacted by telephone 1 day after the cryoablation (unless the esophagectomy will follow directly upon the endoscopic treatment). Finally, the patient may experience some temporary mild pain which can be treated with acetaminophen if necessary.

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

a) Patient must have a minimum of 2.0 cm of non-ulcerated, non-inflammatory columnar-lined esophagus or squamous esophageal lined tissue suitable for ablation. A patient may be treated with up to 2 zones of ablation
b) Patient is 18 to 80 years of age at the time of consent (inclusive).
c) Patient has provided written Informed Consent Form (IFC) using a form that has been approved by the Institution*s reviewing IRB/EC.
d) Patient is willing and able to comply with study requirements.
e) Patient*s esophagectomy is clinically necessary due to reasons unrelated to this study.
f) Patient is deemed operable per standard institutional criteria.

Exclusion criteria

a) Patient has a known history of unresolved drug or alcohol dependency that would limit ability to comprehend or follow instructions related to IFC, post treatment instructions or follow-up guidelines.
b) Patient refuses or is unable to provide written informed consent.
c) Patient has or is currently undergoing endoscopic ablation therapy within 4 cm from the proposed treatment area including, but not limited to cryospray therapy, laser treatment, photodynamic therapy, multi-polar electro coagulation, endoscopic mucosal resection, radiofrequency ablation or argon plasma coagulation.
d) Patient has esophageal narrowing limiting access to the intended site of ablation.
e) Patient is undergoing or has recently undergone chemotherapy (within 15 days or WBC below normal by institutional criteria or standards).
f) Patient is undergoing or has recently undergone radiation therapy which involved the esophagus (within 15 days or WBC below normal by institutional criteria or standards).

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):	19-11-2011
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	C2 Therapeutics CryoBalloon Ablation System (System)
Registration:	No

Ethics review

Approved WMO
Application type: First submission

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	NL33853.018.10