

# Clinical study to Evaluate the Coldplay CryoBalloon™ Full and Swipe Ablation Systems for the Ablation of Human Esophageal Epithelium in Patients Undergoing Esophagectomy

No registrations found.

|                              |                  |
|------------------------------|------------------|
| <b>Ethical review</b>        | Positive opinion |
| <b>Status</b>                | Recruiting       |
| <b>Health condition type</b> | -                |
| <b>Study type</b>            | Interventional   |

## Summary

### ID

NL-OMON29603

### Source

Nationaal Trial Register

### Brief title

ECCAS-study

### Health condition

Barrett's esophagus  
cryoablation

## Sponsors and support

**Primary sponsor:** C2 Therapeutics

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

## Intervention

## Outcome measures

### Primary outcome

safety and treatment effect of the CryoBalloon™ Ablation Systems. Safety will be evaluated by the incidence of serious, CryoBalloon™ Ablation System-related adverse events. Treatment effect of the CryoBalloon™ 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 performed.

### Secondary outcome

The secondary outcome is device performance: ease of deployment, procedure time, endoscope compatibility, and device malfunction.

## Study description

### Background summary

The objective of this study is to evaluate the safety and treatment effect of the CryoBalloon™ Full and Swipe Ablation Systems for the ablation of human esophageal epithelium in patients scheduled to undergo esophagectomy.

### Study objective

The objective of this study is to evaluate the safety and treatment effect of the CryoBalloon™ Full and Swipe Ablation Systems for the ablation of human esophageal epithelium in patients scheduled to undergo esophagectomy.

### Study design

Before esophagectomy, cryoablation will take place and after esophagectomy, the esophagectomy specimen will be analyzed.

### Intervention

cryoablation using the Cryoballoon Full and Dwipe Ablation Systems

## Contacts

### **Public**

Dept. of Gastroenterology and Hepatology  
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H.T. Künzli  
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The Netherlands

### **Scientific**

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The Netherlands

## Eligibility criteria

### **Inclusion criteria**

Patients must meet ALL of the following criteria to be eligible for participation in the study:

1. A minimum of two (2) areas of non-ulcerated columnar-lined esophagus or squamous-lined tissue suitable for ablation. Each ablation zone should be at least 1cm from the tumor and a minimum of 3cm in length. Sequential ablation zones must be a minimum of 1cm apart.
2. Older than 18 years of age at the time of consent.
3. 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**

Patients must be excluded if ANY of the following criteria are met:

1. Patient refuses or is unable to provide written informed consent.

2. Patient has esophageal narrowing limiting access to the intended sites of ablation.

## Study design

### Design

|                     |                         |
|---------------------|-------------------------|
| Study type:         | Interventional          |
| Intervention model: | Other                   |
| Allocation:         | Non controlled trial    |
| Masking:            | Open (masking not used) |
| Control:            | N/A , unknown           |

### Recruitment

|                           |             |
|---------------------------|-------------|
| NL                        |             |
| Recruitment status:       | Recruiting  |
| Start date (anticipated): | 01-10-2015  |
| Enrollment:               | 5           |
| Type:                     | Anticipated |

## Ethics review

|                   |                  |
|-------------------|------------------|
| Positive opinion  |                  |
| Date:             | 31-08-2015       |
| Application type: | First submission |

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 43660  
Bron: ToetsingOnline  
Titel:

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

No registrations found.

## In other registers

| Register | ID             |
|----------|----------------|
| NTR-new  | NL5287         |
| NTR-old  | NTR5394        |
| CCMO     | NL53312.018.15 |
| OMON     | NL-OMON43660   |

## Study results

### Summary results

Schölvinck DW, Künzli HT, Kestens C, et al. Treatment of Barrett ' s esophagus with a novel focal cryoablation device : a safety and feasibility study. Endoscopy 2015.