

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

Gepubliceerd: 31-08-2015 Laatste bijgewerkt: 15-05-2024

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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29603

Bron

NTR

Verkorte titel

ECCAS-study

Aandoening

Barrett's esophagus
cryoablation

Ondersteuning

Primaire sponsor: C2 Therapeutics

Overige ondersteuning: C2 Therapeutics

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

cryoablation using the Cryoballoon Full and Dwipe Ablation Systems

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-10-2015
Aantal proefpersonen:	5
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	31-08-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 43660
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

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.