Clinical trial to investigate the safety and efficacy of the cryoballon swipe ablation system

Gepubliceerd: 26-10-2016 Laatst bijgewerkt: 18-08-2022

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

Samenvatting

ID

NL-OMON23166

Bron
NTR

Verkorte titel
Swipe - dose escalation

Aandoening

Barrett's esophagus, Barrett's dysplasia, Cryo ablation, Cryo therapy, Barrett's slokdarm, Barrett gerelateerde dysplasia, Cryo ablatie, Cryo therapie

Ondersteuning

Primaire sponsor: C2 Therapeutics, Inc.
Overige ondersteuning: C2 Therapeutics, Inc.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1) Safety will be evaluated by the incidence of Dose-related SAEs
2) Efficacy (eradication percentage as determined with the EGD-AC plus histological evidence

of eradication of BE, after circumferential treatment with the therapeutic dose).

Toelichting onderzoek

Achtergrond van het onderzoek

The objective of this study is to evaluate the safety and efficacy of the CryoBalloon Swipe Ablation System for the ablation of dysplastic Barrett’s epithelium, in increasing doses.

Onderzoeksopzet

2 months (+/- 2 weeks) post baseline treatment

Onderzoeksproduct en/of interventie

Patients with a Barrett's Esophagus will be treated with the cryoballoon swipe system. This includes a first treatment covering 50% of circumference and over a length of 3 cm. Patients in phase II will subsequently be treated on the residual 50% of circumference at a second treatment with the swipe system.

The cryoballoon swipe system is an ablative device that freezes (ablates) the esophageal mucosa over a length of 3 cm.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients with flat-type (Paris type 0-IIb) BE esophagus, with an indication for ablation therapy, meaning:

• Diagnosis of LGD or 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2017
Aantal proefpersonen:	18
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	26-10-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5912
NTR-old	NTR6191
Ander register	CP-0018 : C2 Therapeutics

Resultaten