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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23166

Source
NTR

Brief title
Swipe - dose escalation

Health condition

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

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

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).

Secondary outcome

1. Incidence of all serious and non-serious adverse events up to 30 days post-treatment

2. Post-procedure pain in the area of the cryoablation treatment (scored on a 1 to 10- point VAS),

3. Efficacy, defined as the regression percentage at the first follow-up endoscopy, after 1 treatment covering 50% of circumference, with the therapeutic dose

4. Efficacy for treatment with CryoBalloon Swipe ablation system, defined as the proportion of patients with >80% regression of BE after 1 semicircumferential resp. fully circumferential treatment

Study description

Background summary

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.

Study design

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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2017
Enrollment:	18
Type:	Anticipated

Ethics review

Positive opinion

Date:	26-10-2016
Application type:	First submission

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
NTR-new	NL5912
NTR-old	NTR6191
Other	CP-0018 : C2 Therapeutics

Study results