The STEAM-BE study

No registrations found.

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

Summary

ID

NL-OMON28412

Source
NTR

Brief title
The STEAM-BE study

Health condition

Barrett's esophagus

Sponsors and support

Primary sponsor: Academic Medical Center, Amsterdam (AMC)
Source(s) of monetary or material Support: Aqua Medical, Inc.

Intervention

Outcome measures

Primary outcome

Safety will be assessed by the incidence and severity of any complications that are associated with the vapor ablation throughout the follow-up period.

The primary efficacy endpoint is the complete regression of intestinal metaplasia with each vapor ablation dose at 6-8 weeks follow-up as ascertained by endoscopic visualization and histopathologic evaluation.

Secondary outcome

Feasibility, tolerability, dose-effects

Study description

Study objective

This study will test the hypothesis that vapor ablation of Barrett esophagus is feasible and safe, and will result in regression of intestinal metaplasia to squamous epithelium.

Study design

Baseline endoscopy, follow-up endoscopy after 6-8 weeks to assess the primary endpoints.

Intervention

Single treatment session with Aqua Medical Focal Vapor Ablation System

Per patient, four ablations with varying doses will be applied in the Barrett's epithelium.

Contacts

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Eligibility criteria

Inclusion criteria

Inclusion:

a. Subject is between 22 ¨C 85 years of age.

b. Subject should have Barrett esophagus, with either:

I. Barrett esophagus, circumferential extent ≥ 2 cm or tongues ≥ 3 cm, with an indication for ablation therapy, either:

i. Flat low grade dysplasia (LGD)

ii. Flat high grade dysplasia (HGD)

iii. Residual Barrett after removal of visible lesions, containing any grade of dysplasia, or early adenocarcinoma amendable for endoscopic treatment (mucosal or superficial submucosal disease, with well to moderately differentiation and without lymphovascular invasion).

II. Barrett esophagus containing a visible lesion with a type 0-IIa, 0-IIb or 0-IIc component, that requires endoscopic resection

c. Hiatal Hernia < 10cm

d. Subject has signed the informed consent form and is able to adhere to study visit schedule.

Exclusion criteria

Exclusion:

a. Subject has any condition that in the opinion of the PI preclude enrollment into the trial.

b. Subject has had a prior RF or cryoablation procedure

c. Subject has predictors for poor regression after ablation therapy, i.e. one of the following:

• In case of prior ER: regeneration of the ER scar with Barrett¡'s mucosa, OR

• Active reflux esophagitis grade C or D

• Esophageal narrowing pre-treatment with an estimated diameter <20mm

• Absence of squamous islands in the BE

d. Subject has any significant multisystem diseases.

e. Subject has a body mass index (BMI) greater than 40 kg/m2.

f. Subject has a hiatal hernia > 10cm

g. Subject has known moderate/severe gastroparesis

h. Subject is currently enrolled in other potentially confounding research.

i. Subject has an esophageal stenosis preventing the passage of an endoscope

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):	01-11-2018
Enrollment:	9
Type:	Anticipated

Ethics review

Positive opinion

Date:	07-09-2018

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 49629
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7270
NTR-old	NTR7468
CCMO	NL67326.018.18
OMON	NL-OMON49629

Study results