First in-human study on the Safety, Tolerability and Efficacy of the Aqua Medical focal vapor ablation system, for the eradication of Barrett*s Esophagus

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The aim of the current study is to assess the feasibility, safety and efficacy of the Steam ablation System for eradication of small BE areas

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON49629

Source
ToetsingOnline

Brief title
The STEAM-BE study

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms benign

Synonym
Esophageal Carcinoma, Intestinal Metaplasia

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Aqua Medical, Inc.,Aqua Medical;Inc.

Intervention

Keyword: Ablation therapy, Barrett's esophagus, Endoscopic treatment, Esophageal dysplasia

Outcome measures

Primary outcome

Safety:

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

Included in this assessment will be the proportion of subjects with any of the following outcomes from initiations of vapor ablation therapy and completion of the 6-8 week evaluation: (1) death, or (2) medical morbidity associated with the device and/or vapor ablation, including perforation, hemorrhage, scarring or stricture formation.

Efficacy:

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

Other evaluations include, but are not limited to the following:

* Deployment ease/scope compatibility.

* Device malfunctions.

* Time of catheter deployment.

* Adverse events.

* Stricture formation at 6 to 8 weeks.

* Patient Pain.

* Histological evaluation of treatment zone at 6 to 8 weeks for presence of

residual Barrett*s Esophagus.

* Histologic evaluation of direct ablation effects in the resected lesion in

group 2.

Study description

Background summary

Barrett's esophagus (BE) is a premalignant disease that may cause esophageal adenocarcinoma. This particular cancer is one of the most rapidly increasing and deadliest cancers in the Western world. Patients with BE are up to 40 times more at risk of developing esophageal adenocaricinoma than individuals without BE. Once diagnosed with BE, patients enter a life-long surveillance programme in which upper gastrointestinal endoscopies with biopsies are performed to survey the progression of Barrett's tissue to cancer.
The presence of dysplasia or cancer in the BE, is a direct indication for treatment. The most important first step in the treatment of BE is removal of any visible lesion with endoscopic resection. The residual, flat BE segment should then be eradicated with ablation therapy. During the last 20 years, many different technologies have been evaluated for the treatment of BE. Radiofrequency Ablation (RFA) is currently the standard of care, since a large amount of studies has shown that the technique is safe and effective. However, the technique is associated with some important limitatins. The device is rather large, and therefore it cannot be used 'through-the-scope', but an additional removal and introduction of the entire endoscope is always required. This results in a time consuming and technically complicated procedure. Furthermore, the large device cannot be used in patients with an esophageal stenosis, which is a common complication after prior treatment. Moreover, large generators are required and capital investment is necessary. There is need for an easier, safe and effective, through-the-scope ablation system for the treatment of BE.
The Aqua Medical Steam Ablation System (AFVAS) is subject of the current studie and fullfills these criteria. The device is small and hand-held and van be advanced through the working channel of an endoscope. The device can be used in

patients with a stenosis. Prior animal studies showed that a dosing of 3 to 5 seconds results in ablation effects comparable to radiofrequency ablation.

Study objective

The aim of the current study is to assess the feasibility, safety and efficacy of the Steam ablation System for eradication of small BE areas

Study design

Prospective, single-centre, single-arm clinical intervention study

Intervention

The AFVAS consists of the following components:
- Radio-frequency Vapor Generator: A software-controlled RF generator operated through a graphical user interface (GUI) and incorporates a syringe pump that delivers saline to the catheter.
- Disposable, Sterile, Single-Use Catheter: Single-use catheter available in various lengths ranging from 100cm to 170cm. It includes an integrated cable for attachment to the generator and a luer-connector that facilitates connection to the saline delivery tubing. The catheter is available with an integrated hood or can be used with any commercially available distal attachment tip to contain the vapor for ablation.
- Saline Delivery Tubing and Syringe: A saline delivery tubing and syringe (60cc) that provide a means of delivering saline to the catheter during treatment.

Patients will be treated with 4 focal applicaties of approximately 2 squared centimeters per application. Patients with a visible lesion will be treated with 1 to 2 applications, based on the length of the lesion.

Study burden and risks

Patients in the current study have an indication for treatment, and normally they would have had an upper gastrointestinal endoscopy with the standard treatment. During this endoscopy, we now treat small BE areas with Steam Ablation. The follow-up endoscopy will be scheduled earlier, for careful imaging and biopsies. This is identical to standard care. From that moment, patients will be treated with the standard treatment.
It is hard to evaluate whether patients will have to undergo an extra endoscopy for the purpose of this study, since multiple treatment endoscopies are required for the standard treatment in any case. The technique is tested safe in animal studies, and the dosing for the current study shows comparable effects to the standard treatment in the animal lab. We treat only very limited areas (2 squared centimeters), which will be associated with a low risk for

complications.

After the procedure, patients will be called 3 times to assess how they are doing and to evaluate adverse events. Patients will be asked to rate their pain scores in an online diary during the first 14 days after treatment. Apart from that, follow-up care is identical to standard care.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

a. Subject is between 22 * 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 with a visible lesion with a type 0-IIa, -IIb or -IIc component, requiring 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

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 phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-02-2019
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	Aqua Medical Focal Vapor Ablation System (AFVAS)
Registration:	No

Ethics review

Approved WMO Date:	20-12-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-06-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 28412
Source: NTR
Title:

In other registers

Register	ID
Other	29503 (kandidaattrial nummer NTR)
CCMO	NL67326.018.18
OMON	NL-OMON28412