Study on the Safety, Tolerability and Efficacy of the Aqua Medical focal vapor ablation system, for the eradication of Barrett's Esophagus - part 2

Published: 13-02-2020
Last updated: 15-05-2024

Vapor ablation can effectively and safely eradicate short BE segments

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON20279

Source
NTR

Brief title
STEAM-BE 2

Condition

- Gastrointestinal neoplasms malignant and unspecified

Health condition

Barrett esophagus, Barrett neoplasia

Research involving
Human

Sponsors and support

Primary sponsor: Aqua Medical, Inc.

Source(s) of monetary or material Support: Aqua Medical research grant

Intervention

- Medical device

Explanation

Outcome measures

Primary outcome

BE surface regression after 8-12 weeks FU, incidence of adverse events

Secondary outcome

Feasibility to ablate the entire area as intended, duration of ablation, device malfunction, pain scores

Study description

Background summary

We will assess the feasibility, safety and efficacy of Aqua Medical focal Vapor ablation for the treatment of short segment Barrett's esophagus. Vapor ablation is a new method for eradication of Barrett's esophagus and uses the energy of heated, vaporized water to ablate the Barrett's mucosa and to facilitatie regrowth of normal squamous epithelium under acid suppression. Different catheters are available and in the current study we use a focal hood-based catheter and a standardized dose of 3 seconds will be used. In total, 19 patients will be enrolled and treated with side-by-side focal applications of vapor ablation, to assess the feasibility, safety and efficacy of treating short segment Barrett's esophagus with Focal Vapor ablation. The study consists of 3 phases: in phase I, 3 patients will be included and the catheter will be introduced to assess whether all areas could be targeted in a resonable timeframe as compared to focal RFA, no treatment will be performed in this phase. If this phase will be successfully completed, we will continue to phase II. In Phase II, 6 patients will be included and treated circumferentially at the GEJ. If we will be able to ablate the entire GEJ in a reasonable timeframe and in absence of related complications, we will continue to Phase III. In this final phase, we will include 10 patients with short segment BE to treat the entire BE segment. A follow-up endoscopy will be performed after 8-12 weeks to assess the BE surface regression and for histologic sampling.

Study objective

Vapor ablation can effectively and safely eradicate short BE segments

Study design

Baseline, 6-8 weeks FU

Intervention

Vapor ablation

Contacts

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Eligibility criteria

Age
Adults (18-64 years)
Adults (18-64 years)

Inclusion criteria

Flat Barrett's esophagus (BE) with an indication for ablation therapy (either flat confirmed LGD, flat HGD, or residual flat BE after endoscopic resection of early, non-flat BE neoplasia)

Exclusion criteria

Presence of visible lesions, history of advanced BE neoplasia (either sm2+, LVI+ or G3+).

Study design

Design

Study phase:	N/A
Study type:	Interventional
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-06-2021
Enrollment:	19
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Approved WMO

Date:	20-05-2020
Application type:	First submission
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389

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Study registrations

Followed up by the following (possibly more current) registration

ID: 55125
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8369
CCMO	NL73052.018.20
OMON	NL-OMON55125

Study results