The STEAM-BE study

Gepubliceerd: 07-09-2018 Laatst bijgewerkt: 15-05-2024

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.

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

Samenvatting

ID

NL-OMON28412

Bron
NTR

Verkorte titel
The STEAM-BE study

Aandoening

Barrett's esophagus

Ondersteuning

Primaire sponsor: Academic Medical Center, Amsterdam (AMC)
Overige ondersteuning: Aqua Medical, Inc.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-11-2018
Aantal proefpersonen:	9
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	07-09-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49629
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten