5 year follow-up after treatment with radiofrequency ablation for Barrett's esophagus containing HGIN or early cancer.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27049

Source
NTR

Health condition

Barrett's esophagus / Barrett slokdarm
Barrett's cancer / Barrett kanker
Barrett's neoplasia
Barrett's dysplasia
Radiofrequency ablation

Sponsors and support

Primary sponsor: Academic Medical Centre Amsterdam, Department of Gastroenterology and Hepatology
Source(s) of monetary or material Support: Barrx Medical Inc. Sunnyvale, California, US

Intervention

Outcome measures

Primary outcome

1. Rate of complete histological remission of dysplasia and cancer at 5-yr follow-up;

2. Rate of complete endoscopic and histological eradication of IM (including biopsies obtained from neosquamous mucosa) at 5-year follow-up.

Secondary outcome

1. Prevalence of subsquamous IM in neosquamous biopsies and ER-specimens;

2. Prevalence of IM below the Neo Z-line during 5-year follow-up visits;

3. Adverse events.

Study description

Background summary

The purpose of this project is to report on the 5-year outcomes of 4 previously published, IRB-approved, single-centre pilot trials (AMC-I/II/IV and EURO-I), evaluating long-term safety and efficacy of radiofrequency ablation for eradication of BE containing high-grade intraepithelial neoplasia or early cancer.

Study objective

We hypothesize that radiofrequency ablation (RFA) is safe and effective after 5-year follow-up, for the eradication of Barrett's esophagus (BE) containing neoplasia.

Study design

T=60: Single visit at 5-year follow up after the first treatment session.

Intervention

1. Endoscopic surveillance with biopsies according to the Seattle protocol;

2. EUS;

3. Endoscopic resection of the neosquamous epithelium.

Contacts

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Eligibility criteria

Inclusion criteria

1. All eligible patients treated with RFA (AMC-I/II, AMC-IV and EURO-I), according to the aforementioned study protocols, who are now being followed-up endoscopically in the AMC or referral centre within the Netherlands;

2. Written informed consent.

Exclusion criteria

No justification for further follow-up due to (unrelated) comorbidity, or otherwise.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)

Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2011
Enrollment:	55
Type:	Actual

Ethics review

Positive opinion

Date:	14-06-2011
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	NL2797
NTR-old	NTR2938
Other	METC AMC : 10/326
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

1. Gondrie JJ, Pouw RE, Sondermeijer CM, Peters FP, Curvers WL, Rosmolen WD, Ten KF, Fockens P, Bergman JJ. Effective treatment of early Barrett's neoplasia with stepwise circumferential and focal ablation using the HALO system. Endoscopy 2008;40:370-379;
2. Gondrie JJ, Pouw RE, Sondermeijer CM, Peters FP, Curvers WL, Rosmolen WD, Krishnadath KK, Ten KF, Fockens P, Bergman JJ. Stepwise circumferential and focal ablation of Barrett's esophagus with high-grade dysplasia: results of the first prospective series of 11 patients. Endoscopy 2008;40:359-369.
3.Phoa KN, Pouw RE, van Vilsteren FG, Sondermeijer CM, Ten Kate FJ, Visser M, Meijer SL, van Berge Henegouwen MI, Weusten BL, Schoon EJ, Mallant-Hent RC, Bergman JJ. Gastroenterology. 2013 Mar 28. pii: S0016-5085(13)00460-5 (Epub ahead of print)