Outcomes for patients undergoing endoscopic therapy for Barrett’s related neoplasia: over 10-year experience from the Dutch Barrett Expert Centers

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29089

Source
Nationaal Trial Register

Brief title
The BEC cohort

Health condition

Barrett's esophagus; Barrett's related neoplasia

Sponsors and support

Primary sponsor: Lead site:
Academic Medical Center Amsterdam (AMC)

Collaborating centers:
• Sint Antonius Hospital Nieuwegein
• Catharina Hospital, Eindhoven
• University Medical Center, Utrecht
• Isala Clinics, Zwolle
• Erasmus Medical Center, Rotterdam
• Haga Hospital, Den Haag
• University Medical Center, Groningen

Source(s) of monetary or material Support: Academic Medical Center Amsterdam (AMC)

Intervention

Outcome measures

Primary outcome

The primary objective is to determine the proportion of patients with successful eradication of BE after endoscopic therapy. The primary endpoint will be the proportion of patients with a successful complete eradication of Barrett's neoplasia (CE-Neo) after the treatment phase.

Secondary outcome

Secondary endpoints include:

• The durability of a complete eradication of neoplasia and BE during follow-up, with follow-up determined as the interval between the first negative control endoscopy and the last follow-up endoscopy.

• Failure for sustained CE-IM during FU is defined as recurrent visible BE (c>1 according to current guidelines)(10), independent of histology. If the patient was defined as CE-IM after the treatment phase with still some small BE islands present, this patient will be considered as sustained CE-IM during FU.

• Only the patients with CE-IM at the end of the treatment phase will be included in this analysis.

• Failure for sustained CE-neo during FU is defined as recurrent visible BE (c>1 according to current guidelines)(10) with HGD or EAC in biopsies.

• Only the patients with CE-neo at the end of the treatment phase will be included in this analysis.

• The safety after endoscopic therapy for BE

• The incidence of complications such as a perforation or a stenosis will be assessed.

• Predictors for a poor outcome after treatment

• Predictors for a recurrence during follow-up

• The optimum follow-up intervals after a CE-IM will be established

Study description

Background summary

• Esophageal adenocarcinoma (EAC) is highly lethal with a 5-years survival of only 10-15%. The main histologic risk factor for development of EAC is the presence of Barrett’s esophagus (BE). BE can develop from non-dysplastic BE, to low (LGD) and high grade dysplasia (HGD) and, eventually, EAC. Currently, a combined approach of endoscopic resection and endoscopic ablation therapy is the established treatment for eradicating Barrett’s related neoplasia. The organization of BE care in the Netherlands is unique when compared to the rest of the world: the care for all BE patients is centralized in eight Barrett Expert Centers (BEC) with an intensive cooperation and, as a result, homogeneous diagnosis and treatment. However, the overall outcomes for these centers are unknown. The purpose of the study is to determine the state-of-the-art results of endoscopic treatment for Barrett’s esophagus.

Study design

* First treatment endoscopy

* End of the endoscopic treatment phase, defined as the last endoscopy with endoscopic treatment performed.

* Last follow-up endoscopy

Intervention

Endoscopic treatment of Barrett's esophagus by means of endoscopic resection (either endoscopic mucosal resection (EMR) or endoscopic submucosal dissection (ESD)), radiofrequency ablation (RFA) or a combination thereof.

Contacts

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Eligibility criteria

Inclusion criteria

1) Males or females, all ages

2) Presence of Barrett’s esophagus, with presence of intestinal metaplasia in histologic assessment.

3) Referred for work-up in a BEC from 1/1/2007 to the moment of data collection.

4) Scheduled for endoscopic eradication therapy of BE

5) No written or oral refusal to use subject’s data

Exclusion criteria

1) Objection against participation in this study, through an opt-out card or e-mail

2) Referral for surgery after the work-up endoscopy for advanced EAC

3) Presence of non-dysplastic BE without an indication for treatment

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2018
Enrollment:	2000
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

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	NL7039
NTR-old	NTR7244
Other	METC AMC : W18_086

Study results