The identification and validation of risk factors to enable objective risk-stratification to predict malignant progression in Barrett’s Esophagus: a prospective multi-center study in community hospitals in the Amsterdam region

No registrations found.

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

Summary

ID

NL-OMON24029

Source
NTR

Brief title
Rebus-2

Health condition

Barrett's esophagus; Barrett's related neoplasia

Sponsors and support

Primary sponsor: Department of Gastroenteroogy and Hepatology, Amsterdam University Medical Centres (Amsterdam UMC)
Source(s) of monetary or material Support: Department of Gastroenteroogy and Hepatology, Amsterdam UMC

Intervention

Outcome measures

Primary outcome

Primary Objective: To assess endoscopic and clinical risk factors for progression to high-grade dysplasia (HGD) or esophageal adenocarcinoma (EAC) in a large prospective cohort of BE patients from community hospitals aiding objective risk stratification.

Secondary outcome

Secondary Objectives:
- To acquire high-resolution endoscopic images and videos to aid the training and validation of a CAD system to improve endoscopic detection of early neoplasia in BE patients.
- To create a community-based BE surveillance registry to recruit patients for future studies.

Study description

Background summary

Endoscopic surveillance of patients with a Barrett’s esophagus (BE) is crucial to detect neoplasia and its precursor lesions at a stage early enough to be curatively treated, if possible, even endoscopically. The effectiveness and efficiency of the current endoscopic surveillance is questionable as most of the data on risk factors was derived from tertiary care centers or from cohorts with limited surveillance time or surveillance quality. Improving risk-stratification would allow for better endoscopic surveillance. Patients could be stratified into a high-risk or a low-risk group so surveillance intervals can be tailored and the clinical and economic burden of endoscopic surveillance can be reduced.

Study objective

Patients could be stratified into a high-risk or a low-risk group so surveillance intervals can be tailored and the clinical and economic burden of endoscopic surveillance can be reduced.

Study design

Planned surveillance endoscopies according to the Dutch guidelines for NDBE

Contacts

Public
Amsterdam UMC
R.E. Pouw

020-4447135 (research fellow M.W. Chan)
Scientific
Amsterdam UMC
R.E. Pouw

020-4447135 (research fellow M.W. Chan)

Eligibility criteria

Inclusion criteria

- Aged between 18 and 75 years
- Endoscopic and histological evidence of NDBE (defined as intestinal metaplasia without dysplasia) with a circumferential extent of ≥2 cm and a total maximum extent of ≤10 cm
- Ability to provide a written informed consent

Exclusion criteria

- Visible lesions in the esophagus suspicious for neoplasia during the first endoscopy (according to the Paris classification)
- History of HGD or EAC in the esophagus
- Unfit for endoscopic surveillance or inability to obtain biopsies
- History of endoscopic or surgical treatment for esophageal dysplasia or EAC
- History of esophageal surgery other than fundoplication
- Presence of grade C or grade D erosive esophagitis (according to Los Angeles classification)
- Refusal or inability to provide written informed consent

Study design

Design

Study type:	Observational non invasive

Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	10-05-2020
Enrollment:	700
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N/A

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	NL8474
Other	METC AMC : W20_154 # 20.192

Study results

Summary results
N/A