

Detection of palisade vessels as a landmark of the end of Barrett's esophagus

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To assess the usefulness of NBI in the visualisation of PVs in Western BE patients (in this study using the new Excera III NBI-system), to investigate the discordance between the Japanese and Western definition of the distal end of the Barrett's...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational invasive

Summary

ID

NL-OMON37487

Source

ToetsingOnline

Brief title

PALVES

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym

esophageal metaplasia, precursor of esophageal cancer

Research involving

Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis

Source(s) of monetary or material Support: Hoogleraargelden Prof. dr. Weusten

Intervention

Keyword: Barrett's esophagus, Gastric folds, Narrow Band Imaging, Palisade vessels

Outcome measures

Primary outcome

- 1) To investigate the feasibility of NBI for the detection of PVs in Western BE patients, using the new Olympus Excera III endoscopy system,
- 2) Compare the yield of NBI in the detection of PVs with that of white light videoendoscopy.

Secondary outcome

- 1) To elucidate the optimal endoscopic condition to visualize the distal end of PVs.
- 2) To evaluate the discordance in the distal margin of BE using two different landmarks.
- 3) To assess the clinical relevance of this discordance by evaluating the presence of intestinal metaplasia on biopsies taken from the area of discordance.
- 4) To assess the interobserver variability for the location of the distal margin of the Barrett epithelium using the palisade vessels as a landmark, and compare this with the interobserver variability of the location of the distal margin of the Barrett's epithelium using the top of the gastric folds as a landmark.

Study description

Background summary

The incidence of Barrett's related esophageal adenocarcinoma is gradually increasing worldwide. However, discrepancies exist in the endoscopic definition of Barrett's Esophagus (BE) between the Western world and Japan. According to the Western criteria, the distal end of the BE is defined by the proximal end of gastric folds, whereas in Japan the distal end of palisade vessels (PVs) defines the distal margin of the BE. PVs are thought to be rather faint, or even absent in a significant proportion of Western BE patients. Consistency in the definition of BE is thought to be essential for better understanding and further investigation of BE. The use of Narrow Band Imaging (NBI), one of image-enhancing endoscopic modalities, makes vessels more readily visible and enhances contrast in mucosal structures and vessels, and may therefore help to show PVs clearly. The new Olympus Excera III endoscopy system combines bright NBI with dual focal high-resolution endoscopy, and may in this study more easily recognize and visualize PVs, even in Western BE patients.

Study objective

To assess the usefulness of NBI in the visualisation of PVs in Western BE patients (in this study using the new Excera III NBI-system), to investigate the discordance between the Japanese and Western definition of the distal end of the Barrett's segment, to evaluate the clinical relevance of this discordance, and to study the interobserver variability of both Western and Japanese criteria.

Study design

Prospective, mono-center, single arm, not randomised.

Study burden and risks

The burden for the patients is negligible because the patients are scheduled for upper endoscopy as part of normal clinical care (no additional endoscopies will be performed). This study needs additional five minutes for recording with photos/video and for taking additional biopsies.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- 1) Age 18-80 years
- 2) BE with a minimum length of C2M2 (segment of minimally 2 cm circumferential Barrett epithelium) as pointed by prior endoscopic examination(s)
- 3) Subject who agrees to participate, fully understands the content of the informed consent form, and signs the informed consent form

Exclusion criteria

- 1) (Previous) biopsies showed high grade dysplasie or early adenocarcinoma of the distal 2 cm of the esophagus.
- 2) Prior endoscopic treatment for BE or Barrett's dysplasia/cancer (e.g. radiofrequency ablation, endoscopic mucosal resection, multi-band mucosectomy)
- 3) Prior surgical intervention for the lower part of the esophagus or the upper part of the stomach
- 4) Subject being pregnant or planning a pregnancy
- 5) Esophageal stricture preventing passage of endoscope
- 6) Subject suffering from unstable psychiatric disorder(s)
- 7) Subject unable to give the informed consent
- 8) Uncorrectable clotting disorders, esophageal varices, or other conditions precluding taking

biopsies

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 14-06-2012

Enrollment: 25

Type: Actual

Medical products/devices used

Generic name: EXERA III Narrow Band Imaging system

Registration: Yes - CE intended use

Ethics review

Approved WMO

Date: 27-04-2012

Application type: First submission

Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
CCMO	NL39542.100.12