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

Submission date
27/01/2014

Recruitment status
No longer recruiting

Registration date
01/04/2014

Overall study status
Completed

Last Edited
24/01/2019

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The definition of the transition between esophagus and stomach (EGJ) for a diagnosis of Barrett s esophagus (BE) is not uniform: in Western guidelines the EGJ is located at the top of the gastric folds (GF) in expiration. In contrast, in Japan the EGJ is defined by the distal end of the palisade vessels (PV), little vessels perforating the mucosa in the distal esophagus. Yet, PV are faint and often poorly visible in Western patients. Narrow Band Imaging (NBI) enhances contrast in mucosal structures and vessels. The new Olympus EXERA III endoscopy system combines bright NBI with dual focal high-resolution endoscopy, and may more easily visualize PV, even in Western BE patients. The aim of the study is to evaluate the detection rate of PV using the EXERA III system, to quantify the discordance between the Western and Japanese criteria for the distal border of BE, and to evaluate the presence of intestinal metaplasia (IM) in this zone of discordance (ZoD), in Western BE patients.

Who can participate?
All BE patients scheduled for surveillance endoscopy.

What does the study involve?
For this study additional images of the EGJ are taken for further analyses. In case of a zone of discordance, biopsies are taken from this zone. Furthermore routine biopsying is performed for surveillance of BE.

What are the possible benefits and risks of participating?
There are no benefits in participating. In patients with a zone of discordance 2 extra biopsies are taken, with accompanying risks.

Where is the study run from?
St. Antonius Hospital, Nieuwegein, the Netherlands.

When is the study starting and how long is it expected to run for?
The study started in May 2012 and finished in June 2013.

Who is funding the study?
St. Antonius Hospital, Nieuwegein, the Netherlands.

Who is the main contact?
Dirk Schölvinck
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Contact information

Type(s)
Scientific

Contact name
Dr Bas Weusten

Contact details
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Detection of PALisade VESsels as a landmark for the distal Barretts esophagus in Western population

Acronym
PALVES

Study objectives
The improved Narrow Band Imaging endoscopy system (EXERA III) may more easily facilitate the detection of palisade vessels (PV) in the Western BE population, and enable a comparison between the Western and Japanese criteria for the distal BE. The aim of this study was therefore to prospectively evaluate the detection rate of palisade vessels using NBI (EXERA III system), to quantify the discordance between the Western and Japanese criteria for the distal border of the BE, and to evaluate the clinical relevance of this discordance.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Medical Ethics Committee - United Committees for Human Research (Verenigde Commissies Mensgebonden Onderzoek), 27/04/2012, R12.003

Study design
Prospective single center study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Barrett's esophagus, endoscopy

Interventions
Taking biopsies from the discordant area to make a histological diagnosis of BE. Based on realtime endoscopy, endoscopic images and biopsies we try to assess the visibility of palisade vessels and the possible implications when these palisade vessels are not located at the same level of the gastric folds.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
The proportion of patients with visible palisade vessels using white light endscopic imaging and using Narrow Band Imaging (EXERA III endoscopy system)

Key secondary outcome(s))
1. The proportion of patients with visible PVs with or without air inflation, and in a forward view or a retroflex view
2. The degree of discordance between the location of the proximal ends of the gastric folds and the distal end of the PVs
3. The degree of discordance in the location of the proximal ends of the gastric folds between the condition with and without air inflation
4. The proportion of biopsies containing intestinal metaplasia on histological evaluation among the BE area, the area of discordance (area between the top of gastric folds and distal end of PVs), and the gastric area (area just below the distal ends of PVs)
5. The interobserver agreement for the rates of visualisation of PVs and the top of the gastric folds on each condition

Completion date
01/07/2013

Eligibility

Key inclusion criteria
1. Age 18-80 years
2. BE with a minimum length of circumferential/ maximal (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

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
80 years

Sex
All

Key exclusion criteria
1. (Previous) biopsies of the most distal 2 cm Barrett esophagus (according to CM-classification) showed high grade dysplasia or esophageal adenocarcinoma (EAC)
2. Prior endoscopic treatment for BE or Barretts dysplasia/cancer (e.g. radiofrequency ablation, endoscopic mucosal resection, multi-band mucosectomy
3. Prior surgical invervention 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

Date of first enrolment
01/05/2012

Date of final enrolment
01/07/2013

Locations

Countries of recruitment
Netherlands

Study participating centre
Koekoekslaan 1
Nieuwegein

Netherlands
3435 CM

Sponsor information

Organisation
St. Antonius Hospital (Netherlands)

ROR
https://ror.org/01jvpb595

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
St. Antonius Hospital (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2016	24/01/2019	Yes	No