Barrett*s Esophagus and Adenocarcinoma STudy (EAST); The inflammatory background

Published: 11-08-2009
Last updated: 06-05-2024

To determine the composition of immune cells and the expression of immunological factors in normal squamous esophagus, RE, BE and EAC.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal inflammatory conditions
Study type	Observational invasive

Summary

ID

NL-OMON37304

Source
ToetsingOnline

Brief title
Barrett*s Esophagus and Adenocarcinoma STudy (EAST)

Condition

- Gastrointestinal inflammatory conditions
- Gastrointestinal neoplasms malignant and unspecified

Synonym
Barrett's esophagus; intestinal metaplasia; replacement of normal esophageal mucosa by an intestinal type of mucosa

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,Maag Lever Darm

stichting

Intervention

Keyword: Barrett's Esophagus, esophageal cancer, inflammation

Outcome measures

Primary outcome

Differences in the composition of immune cells and the expression of

immunological factors between normal squamous epithelium, RE, BE and EAC.

Secondary outcome

Not applicable.

Study description

Background summary

Barrett*s esophagus (BE) is an acquired premalignant condition that results from chronic gastro esophageal reflux disease (GERD) and predisposes to the development of esophageal adenocarcinoma (EAC). In BE, the normal esophageal squamous epithelium is replaced by intestinal columnar epithelium: intestinal metaplasia. The prognosis of EAC is poor and the incidence of EAC is rising faster than that of any other malignancy in the Western world. The pathophysiology of BE is largely unknown, but it is commonly accepted that the disease is initiated by chronic exposure to acid and bile (components of reflux). Diagnostic strategies to identify BE patients and the subgroup at increased risk of developing EAC are currently insufficient and critical to improve.
There is increasing evidence that chronic inflammation in the gastrointestinal tract predisposes to changes in tissue morphology and may lead to development of cancer. As reflux disease may result in inflammation, it is plausible that inflammatory cells, - receptors or - mediators play a role in the esophageal metaplastic and neoplastic tissue transition, contributing to the development of reflux esophagitis (RE), BE and EAC.
Insight in these immunological processes could lead to a better understanding how RE, BE and EAC develop and could pave the way for new diagnostic strategies. Therefore, a study elucidating the pathogenesis of BE and EAC is urgently needed.

Study objective

To determine the composition of immune cells and the expression of immunological factors in normal squamous esophagus, RE, BE and EAC.

Study design

This is a cross-sectional study, in which extra biopsies will be taken during upper gastrointestinal endoscopy at the outpatient Gastroenterology department of the UMC Utrecht adn CMH (BE and EAC groups). Patients with reflux symptoms, aspecific complaints, BE and EAC (associated with BE) scheduled for endoscopy of the esophagus will be asked to participate in this study. A different patient information brochure is distributed for each of the three endoscopy indications (reflux symptoms or aspecific complaints/ BE/ EAC).
During upper gastrointestinal endoscopy the following extra biopsies are taken (if indicated): 5 biopsies in patients without endoscopic abnormalities, 7 in RE, 8 in BE, 8 in EAC in the absence of BE (but with a prehistory of BE) and 11 in EAC in the presence of BE. The biopsies will be obtained from the involved esophageal segments, from normal esophageal squamous epithelium and from the duodenum as a control for intestinal tissue. The selected patients will be asked to complete the *Barrett slokdarm*- questionnaire concerning socio-demographic and medical information and two blood samples (12ml) will be taken by venepuncture. The composition of immune cells and the expression of immunological factors will be assessed in biopsies and blood samples.

Study burden and risks

The burden associated with participation is limited; filling out a questionnaire, which takes 15 minutes, undergoing a venepuncture and extending the duration of the endoscopic procedure with 2 minutes. Patients do not have to bring an additional visit to the hospital. The risk of participation is considered low. A total of 12 ml blood will be withdrawn from the patient and a hematoma may develop after venepuncture. The endoscopical procedures are routinely performed and considered as safe. No minors or incapacitated adults are included in this study. There are no direct benefits for the patients in this study.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
3584CX Utrecht

NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
3584CX Utrecht
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Upper gastrointestinal tract endoscopy for the indications gastro-esophageal reflux disease (GERD), aspecific complaints, BE or BE associated EAC. 2. Patients older then 18 years old. 3. Written informed consent.

Exclusion criteria

1. Pregnancy 2. History of esophagectomy or gastrectomy. 3. Reflux symptoms in the absence of endoscopic RE. 4. Esophageal squamous cell carcinoma. 5. Cardiacarcinoma or EAC not associated with BE. 6. Unable to fill out the questionnaire.;* reflux symptoms in the absence of endoscopic RE
* esophageal squamous carcinoma
* cardiacarcinoma or EAC not associated with BE

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-09-2009
Enrollment:	304
Type:	Actual

Ethics review

Approved WMO Date:	11-08-2009
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	06-04-2011
Application type:	Amendment
Review commission:	METC NedMec

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	NL27098.041.09