Chronic inflammation and development of cancer in the esophagus

Published: 23-10-2007
Last updated: 09-05-2024

To determine which DC populations are present in esophageal tissue of patients with reflux esophagitis and BE. Relate the findings regarding DC populations to other pre-malignant gastrointestinal disorders (IBD).

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

Summary

ID

NL-OMON30962

Source
ToetsingOnline

Brief title
Inflammation and cancer in the esophagus

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms malignant and unspecified

Synonym
Chronic reflux disease, heart burn

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Barrett's esophagus, Cancer, Chronic inflammation, Dendritic cells

Outcome measures

Primary outcome

The main study parameter is a significant difference in the number and type of

DCs in the esophagus of patients with chronic gastro esophageal reflux disease

and BE.

Secondary outcome

- To determine DC populations in blood

- To relate the above-mentioned findings of DC to other pre-malignant

gastrointestinal disorders, i.e., Crohn*s disease and ulcerative colitis.

Study description

Background summary

It is known that chronic inflammation predisposes to development of cancer. In Barrett*s esophagus (BE), a pre-malignant condition of the esophagus, normal squamous epithelium is replaced by intestinal columnar epithelial cells. Its formation coincides with chronic inflammation. BE predisposes to development of adenocarcinoma in the esophagus. Dendritic cells (DCs) play a crucial role in the induction of an immune response, and maintenance of chronic inflammation. DCs are the only antigen presenting cells capable of activating naïve T lymphocytes. Here, we will study which types of DCs are present in inflammatory pre-malignant disease in the esophagus. By identifying the changes in DC activation and its relation to squamous versus columnar epithelial cells, we will be able to pinpoint new therapeutic targets for Barrett*s esophagus and thereby prevent chronic inflammation and the progression to adenocarcinoma.

Study objective

To determine which DC populations are present in esophageal tissue of patients with reflux esophagitis and BE. Relate the findings regarding DC populations to

other pre-malignant gastrointestinal disorders (IBD).

Study design

This is a cohort study, in which extra biopsies will be taken during diagnostic endoscopy at the outpatient clinic in the UMC Utrecht. Patients scheduled for endoscopy of the esophagus or colon for the indications 1) Reflux esophagitis 2) Barrett*s esophagus 3) Ulcerative colitis, or 4) Crohn*s disease will be asked to participate in this study. From each group 20 patients are included in this study. Inclusion of patients in this study protocol will therefore not lead to extra upper or lower gastrointestinal endoscopy. In addition to biopsies we will ask the patient for donation of three tubes (21 ml) of blood and we will as them to fill out two short questionnaires.

Study burden and risks

The patients will undergo endoscopy for diagnostic purposes; during this procedure six to eight extra biopsies will be taken, meaning that patients do not undergo an extra endoscopy. Participation does not involve an increased risk during endoscopy; the procedure will take about two minutes longer. We also ask the patients to fill out two questionnaires and we will ask them to donate three tubes (21 ml) of blood.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
3584 CX Utrecht
Nederland
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
3584 CX Utrecht
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- >= 18 years old
- written informed consent
- upper or lower gastrointestinal tract endoscopy for diagnosis or follow-up of pre-malignant disorder of the gastrointestinal tract

Exclusion criteria

- pregnancy
- esophagectomy, gastrectomy
- total proctocolectomy

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-12-2007
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	23-10-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	18-12-2007
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	12-02-2008
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL18901.041.07