Genetic aspects of Barrett Esophagus

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The present study aims to investigate genetic factors that contribute to the development of BE.

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

Summary

ID

NL-OMON31201

Source
ToetsingOnline

Brief title
GENBAR

Condition

- Gastrointestinal inflammatory conditions
- Gastrointestinal neoplasms malignant and unspecified

Synonym
Barrett Esophagus

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Barrett Esophagus, Esophageal adenocarcinoma, familiar barrett esophagus, polymorphisms

Outcome measures

Primary outcome

•Familial incidence of GERD, BE and EAC in first en second degree relatives of patients with BE in the Netherlands.

Secondary outcome

•Gene-environment interactions on familial susceptibility to GERD and BE

•Incidence of EAC in family members of patients with GERD and BE.

•Reported polymorphisms in BE are predictive for developing BE in relatives of patients with this disorder.

Study description

Background summary

In the last three decades, the incidence of esophageal adenocarcinoma (EAC) has dramatically increased. Most cases of EAC arise in Barrett*s esophagus (BE). There are several risk factors that predispose to BE, such as older age, male gender and gastro-esophageal reflux disease (GERD). There is increasing evidence that an underlying genetic susceptibility may contribute to the development of GERD and BE. Several studies have reported a familial prevalence of BE and EAC.

Study objective

The present study aims to investigate genetic factors that contribute to the development of BE.

Study design

Cohort study in BE-patients and their relatives to investigate the incidence of familial BE and the possible genetic factors contributing to BE and EAC.

Study burden and risks

BE-patients and their relatives will be asked to give a blood sample. The

family members will be offered a gastroscopy to detect the presence of BE. A gastroscopy is considered to be a low risk intervention.

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

Patients:
- Age >= 18 years
- Informed consent
- Participating in the CYBAR study (histological confirmation of diagnosis of BE);Family members:
- Age >= 18 years
- Informed consent

Exclusion criteria

- Unable to fill out questionnaire

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:	Pending
Start date (anticipated):	01-05-2007
Enrollment:	1500
Type:	Anticipated

Ethics review

Approved WMO

Date:	12-07-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL17484.078.07