The role of miRNAs in the biology of Barrett*s esophagus

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Benign neoplasms gastrointestinal
Study type	Observational invasive

Summary

ID

NL-OMON39347

Source
ToetsingOnline

Brief title
The role of miRNAs in the biology of Barrett*s esophagus

Condition

- Benign neoplasms gastrointestinal
- Gastrointestinal neoplasms malignant and unspecified

Synonym
Barret's esophagus

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Barrett's esophagus, esophageal adenocarcinoma, miRNA's

Outcome measures

Primary outcome

The patient part of the study will be finished when sufficient sample series are collected for each group of patients. After this, the study will continue without patient involvement and will consist of analyzing data from patient material.

The primary objective is to generate genome-wide miRNA profiles of patient material (tissue samples and blood).

Secondary outcome

The secondary objectives are to compare miRNA expression profiles to investigate what role differences in miRNA expression have in the development and malignant progression of Barrett's esophagus (See research protocol p. 13).

Study description

Background summary

Barrett*s esophagus is a metaplastic response occurring in a minority of patients with persistent gastro-esophageal reflux disease. Non-dysplastic Barrett's esophagus can develop from inflamed squamous epithelium and progress towards low-grade and subsequently high-grade dysplasia en eventually esophageal adenocarcinoma, but only a small minority of Barrett's esophagus patients will show malignant progression during their lifetime.
Efficient risk stratification methods to identify Barrett's esophagus patients at risk for malignant progression are lacking due to an incomplete

understanding of the mechanisms underlying the development and malignant progression of Barrett's esophagus. MicroRNAs (miRNAs), a class of small regulatory RNA molecules, have been widely implicated in differentiation and carcinogenesis. Currently, little is known regarding the role of miRNAs in Barrett's esophagus, and this study is designed to study the biology of miRNAs in Barrett's esophagus.

Study objective

The primary objective is to generate genome-wide miRNA profiles of patient material (tissue samples and blood).
The secondary objectives are to compare miRNA expression profiles to investigate what role differences in miRNA expression have in the development and malignant progression of Barrett's esophagus.

Study design

The study is designed as a case control study, which will consist of five patient groups.

Study burden and risks

The burden for the patient will consist of additional biopsies and one blood sample taken during esophagogastroduodenoscopy sessions. The study does not require additional esophagogastroduodenoscopy sessions, as an esophagogastroduodenoscopy is performed for clinical reasons. The number of site visits is thus unaltered by participation in the study. The number of additional biopsies taken would approximately be six per patient (squamous epithelium, non-dysplastic Barrett's esophagus and Barrett's esophagus with high-grade dysplasia/early esophageal adenocarcinoma, all in twofold).
No significant risks are associated with the biopsy procedure itself; severe bleeding or perforation of the esophagus are potential severe complications, but occur very rarely. Taken the low risk of additional biopsies, the potential knowledge that could be obtained by this study regarding prevention and surveillance strategy outweighs the hazards associated with the study.
The collection of blood samples is a procedure that is routinely performed and not associated with any serious complications in patients healthy enough to undergo esophagogastroduodenoscopy. A hematoma may form at the puncture site, but it will dissolve by itself within a few days.
Patients will be sent a short questionnaire along with the patient letter. The questionnaire will consist of two questions, regarding smoking and medication use.

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

For the group with advanced esophageal adenocarcinoma > stage 1A :
• Patients older than 18 years with esophageal adenocarinoma with stage 1B or higher that are scheduled for esophagogastroduodenoscopy.
For the high-grade dysplasia or esophageal adenocarcinoma group:
• Patients older than 18 years with Barrett's esophagus and esophageal adenocarinoma until stage 1A (established on the basis of a histological biopsy) that are scheduled for esophagogastroduodenoscopy.
For the non-dysplastic Barrett's esophagus group:
• Patients older than 18 years with long-standing non-dysplastic Barrett's esophagus that are under surveillance and have not shown any signs of malignant progression.
For the gastro-esophgeal reflux disease group patients:
• Patients older than 18 years without Barrett's esophagus but with reflux disease, confirmed

by an esophagogastroduodenoscopy
For the control group patients:
• Patients older than 18 years without Barrett's esophagus or reflux disease, confirmed by an esophagogastroduodenoscopy

Exclusion criteria

• Patients younger than 18 years
• Patients unfit to undergo esophagogastroduodenoscopy.
• Patients in whom no samples of either squamous epithelium, Barrett's esophagus or esophageal adenocarcinoma epithelium could be obtained for different reasons, as judged by the endoscopist
• For the gastro-esophgeal reflux disease group patients: the presence of Barrett's esophagus

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):	13-05-2012
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO

Date:	08-07-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	11-07-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL36064.042.11