The risk of gastric cancer: genetic polymorphisms, Helicobacter pylori virulence factors and lifestyle.

Published: 07-06-2006
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Primary objective:To determine the relative risk of gastric cancer for genetic polymorphisms.Secondary objectives:- To determine the relative risk of gastric cancer for combinations of genetic polymorphisms, H. pylori virulence factors and lifestyle...

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

Summary

ID

NL-OMON30209

Source
ToetsingOnline

Brief title
TRI-GAS

Condition

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

Synonym
gastric cancer, stomach cancer

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: gastric cancer, genetic polymorphisms, Helicobacter pylori, lifestyle

Outcome measures

Primary outcome

Host genetic polymorphisms

Secondary outcome

H. pylori virulence factors

Lifestyle factors

Study description

Background summary

In the Netherlands the incidence of gastric cancer is approximately 2000 cases per year. Patients with gastric cancer usually present at advanced stage, with only limited treatment options. The detection of lesions at high risk of malignant transformation or early gastric cancer at a curable stage would improve morbidity and survival.
However, a population screening program of gastric cancer does not seem appropriate in a country with a relatively low incidence. To identify risk groups that might benefit from screening and surveillance, risk factors for the development of gastric cancer need to be identified.
The risk of gastric cancer for each individual is presumably largely determined by the interaction between host genetic factors, Helicobacter pylori virulence and lifestyle.

Study objective

Primary objective:
To determine the relative risk of gastric cancer for genetic polymorphisms.

Secondary objectives:
- To determine the relative risk of gastric cancer for combinations of genetic polymorphisms, H. pylori virulence factors and lifestyle factors.
- To determine whether susceptibility to H. pylori infection is influenced by host genetic polymorphisms.

Study design

Multicenter case-control study. Risk profiles from patients suffering from gastric cancer will be compared with profiles from a control-group of patients scheduled for gastroscopy.
All patients will be asked to fill out a questionnaire. From both gastric cancer patients and control patients, eight gastric biopsies will be collected. The gastric biopsies will be used to investigate genetic polymorphisms and H. pylori virulence factors.

Study burden and risks

Complications resulting from gastroscopies are rare (about 1 per 3000 gastroscopies), possible complications are bleeding or perforation. The burden of a gastroscopy is usually limited. After participation in this study the participants can directly leave the hospital.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Postbus 2040
3000 CA Rotterdam
Nederland
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Postbus 2040
3000 CA Rotterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Group 1: Patients with gastric cancer
Group 2: Control group: patients scheduled voor gastroscopy

Exclusion criteria

Group 1: Patients with gastric metastases of a distant primary malignancy
Group 2: History of malignancies

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:	Recruiting
Start date (anticipated):	14-07-2006
Enrollment:	255
Type:	Actual

Ethics review

Approved WMO

Date:	07-06-2006
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	NL11178.078.06