The Progression and Regression of precancerous gastric lesions: A prospective cohort study; The PROREGAL study

Published: 23-07-2009
Last updated: 24-05-2024

Identification of patients with a high risk of progression of premalignant gastric lesions, in order to compose guidelines for surveillance and follow up.

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

Summary

ID

NL-OMON53080

Source
ToetsingOnline

Brief title
PROREGAL

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Bacterial infectious disorders
- Gastrointestinal neoplasms malignant and unspecified

Synonym
precancerous lesions of the stomach, Premalignant gastric lesions

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: atrophic gastritis, H. Pylori, intestinal metaplasia, progression

Outcome measures

Primary outcome

Progression of premalignant gastric lesions, both in terms of distribution and

severity.

Secondary outcome

Identification of the risk factors, which play a role in progression or

regression of premalignant gastric lesions.

Evaluation of the existing guideline for premalignant lessions of the stomach.

Evaluation of the correlation between serum pepsinogen I, II and gastrin and

the histological severity and extent and intragastric distribution of

premalignant gastric lesions.

To assess the involvement of genetic risk factors on oxidative dammage induced

by innate immune cells, imuune cell function, and the eradication of

Helicobacter pylori.

Evaluation of current guidelines

Study description

Background summary

The second leading cause of cancer related mortality in the world is gastric

cancer. The highest incidences are found Eastern Asia, Eastern Europe and South America and even though the incidence rate is declining, more cases are found every year due to aging of the world population. In the Netherlands it remains one of the most common cancers with an incidence of 2000 cases a year.
In 1992 Correa described a possible pattern of human gastric carcinogenesis. Helicobacter Pylori is considered as the starting point of this sequence, which leads to atrophic gastritis, intestinal metaplasia and dysplasia and eventually ends in intestinal gastric carcinoma in 1-2%.
Since only 1-2% of the 7000 new cases with precancerous gastric lesions develop gastric carcinoma, it is of interest which patients show progression early on, and which patients to offer surveillance in a certain time period. Even though it is clear that the risk of progression increases with the kind of lesion found, it is not clear which patient progress from, for example, atrophic gastritis to intestinal metaplasia and from intestinal metaplasia to dysplasia. Despite previously conducted studies no consensus exists concerning H. pylori eradication. It is not clear whether H. pylori eradication has any effect on the progression or regression of premalignant lesions. H. pylori eradication has shown to diminish gastritis in infected individuals and to prevent the development of premalignant gastric lesions. However the effect on atrophy, intestinal metaplasia or dysplasia remains a subject of discussion
An earlier retrospective study by De Vries, et al has shown that every year 0,1% of the patients with gastric atrophy, 0,25% of the patients with intestinal metaplasia and 6% of the patients with dysplasia progress to gastric carcinoma. The specific patients who show progression or a constant stadium of the sequence or show regression have not been identified. It is however clear that a combination of H. pylori virulence, host genetic factors and lifestyle is the major part of the risk profile. When it would be possible to identify the effect of Helicobacter pylori eradication and the specific groups of patients with the highest risk of progression, requiring gastric cancer screening and/ or surveillance, guidelines could be made and a uniform approach could be created.

Study objective

Identification of patients with a high risk of progression of premalignant gastric lesions, in order to compose guidelines for surveillance and follow up.

Study design

Observational cohort study; a multicenter, prospective study. The study will be initiated and guided by the Erasmus MC, Rotterdam. Intended participating centers include; VU Medical Center, Amsterdam; Medical Center Leeuwarden, Leeuwarden, Deventer Ziekenhuis, Deventer; Rijnstate Medical Center, Arnhem; Canisius Wilhelmina Ziekenuis, Nijmegen;IJsselland Ziekenhuis, Capelle aan den IJssel; het Sint Fransiscus Gasthuis, Rotterdam, and the AvL-NKI, Amsterdam; Meander Medisch Centrum, Amersfoort, Maasstad ziekenhuis, Rotterdam

Study burden and risks

Patients will beasked to give a blood sample when endoscopy is performed, which barely contains any risks for the participants. Upper gastrointestinal endoscopy with biopsy sampling is considered to be a safe procedure and complications are rare (1 in 3000 endoscopies).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Patients with a previous diagnosis of atrophic gastritis, intestinal metaplasia and/or dysplasia of the gastric mucosa
Age 18 years or older

Exclusion criteria

Previous upper gastrointestinal surgery
Previous diagnosis of gastric cancer or any other maligancy not being in remission
Subjects with severe concomittant illness limiting their expected survival to less than 2 years
Subject with portal hypertension
Subjects with proven CDH1 mutation.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-08-2009
Enrollment:	960
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	23-07-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	23-12-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	25-10-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	29-04-2014
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	21-07-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	31-01-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	06-04-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	08-07-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-10-2021
Application type:	Amendment

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	01-11-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	14-03-2024
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	03-05-2024
Application type:	Amendment
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	NL27171.078.09