

The value of narrowband imaging with magnifying endoscopy in the surveillance of patients with intestinal metaplasia and dysplasia of the gastric mucosa

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To determine the additional value of NBI-ME to conventional endoscopy in the surveillance of patients with intestinal metaplasia and dysplasia, i.e. to evaluate whether the use of NBI-ME is superior to conventional endoscopy in the detection of...

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

Summary

ID

NL-OMON30828

Source

ToetsingOnline

Brief title

NIMGAS

Condition

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

Synonym

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: gastric dysplasia maag, gastric intestinal metaplasia, magnifying endoscopy, narrowband imaging, surveillance

Outcome measures

Primary outcome

The number of detected lesions with histological proven intestinal metaplasia or dysplasia after NBI-ME as compared to the number of detected lesion with histological proven intestinal metaplasia or dysplasia after conventional endoscopy.

Secondary outcome

Correspondence between serologic markers (pepsinogen I, II and gastrin 17) and H. pylori data and histology

Study description

Background summary

In the Netherlands, gastric remains one of the most common cancers with over 2000 new cases every year. Symptoms are generally absent until an advanced stage of disease, when there are limited treatment options. Therefore, diagnosis of pre-malignant gastric lesions before malignant progression could improve the prognosis of these patients. The surveillance of these premalignant lesions could lead to improved survival of these patients. However, the histological diagnosis of these premalignant lesions is usually disregarded in clinical practice, as no guidelines exist for the surveillance or treatment of patients with these lesions. Periodical surveillance is common in dysplasia patients, but not in patients with intestinal metaplasia or atrophic gastritis. Recent investigation have demonstrated that current surveillance of pre-malignant gastric lesions shows great discrepancy with the substantial

gastric cancer risk of these lesions.

Although image quality of standard endoscopes has improved dramatically over the past decades, endoscopic evaluation of the condition of the gastric mucosa still correlates poorly with histological findings. Therefore, a diagnosis of pre-malignant gastric lesions remains dependant on random biopsy sampling during conventional gastroscopy.

A promising technique is narrow-band imaging in combination with magnifying endoscopy (NBI-ME). The principle of this new technique is based on modification of the spectral characteristics of the optical filter in the light source, which leads to enhancement of mucosal structures. With use of different narrow-band filters in combination with image magnification, mucosal structures can be very clearly demonstrated, among others resulting in increased contrast. Therefore it can be expected that the use of this technique for targeted biopsy sampling can increase the diagnostic yield of endoscopy for primary detection of pre-malignant gastric lesions. However, the additional value of narrowband imaging with magnification endoscopy to conventional endoscopy in the surveillance of patients with pre-malignant gastric lesions is yet unclear.

Also serum levels of pepsinogen I and II and gastrin 17 are possible parameters to predict the presence of intestinal metaplasia and dysplasia. However, the exact predictive value of these parameters in a population of patients with intestinal metaplasia and dysplasia is unclear.

Study objective

To determine the additional value of NBI-ME to conventional endoscopy in the surveillance of patients with intestinal metaplasia and dysplasia, i.e. to evaluate whether the use of NBI-ME is superior to conventional endoscopy in the detection of intestinal metaplasia or dysplasia, using histology as reference value.

Study design

1. The presence of serum H. pylori antibodies, pepsinogen and gastrin 17 will be evaluated.
2. Gastroscopy: A single endoscopic procedure, including conventional endoscopy and NBI-ME, will be performed by an expert endoscopist with an endoscope that can be used for both conventional endoscopy and NBI-ME. Biopsy samples will be obtained.

Study burden and risks

Patients will be asked to give a blood sample. Gastroscopy with NBI-ME is considered to be a low risk intervention (complications: less than 1 in 3000 gastroscopies).

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 undergoing a surveillance endoscopy because of a previous diagnosis of intestinal metaplasia or dysplasia of the gastric mucosa

Patients with gastric intestinal metaplasia or dysplasie diagnosed after the start of the study

Exclusion criteria

Coagulopathy uncorrected at the time of endoscopy or thrombocytopenia

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): 09-11-2007

Enrollment: 130

Type: Actual

Ethics review

Approved WMO

Date: 02-10-2007

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	NL18712.078.07