Early detection of gastric cancer and its precursor conditions by endoscopic screening

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

Summary

ID

NL-OMON56730

Source
ToetsingOnline

Brief title
TOGAS

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: Horizon Europe Project 101101252 TOGAS

Intervention

Keyword: early detection, gastric cancer, screening

Outcome measures

Primary outcome

The primary objective of the current protocol is to determine the diagnostic yield (in percentage of detected conditions)of an upper endoscopy to detect (pre)malignant gastric lesions in patients who will require a colonoscopy.

Secondary outcome

• The extra value of endoscopy to serology screening among other approaches.

• The prevalence of other upper gastrointestinal conditions in the study population.

• The endoscopist*s performance to detect relevant gastric lesions, as well as oesophageal or duodenal conditions.

• Safety of the procedure and the participants* satisfaction, including also reasons not to participate.

• The diagnostic value of a positive FIT in detecting upper gastrointestinal lesions.

Study description

Background summary

Although the incidence of gastric cancer is decreasing across the globe, including Europe, the burden of the disease is still substantial and will not disappear in the foreseeable future unless effective measures of prevention are implemented. A key issue is the lack of established programs for early detection of gastric cancer and its precursor conditions in Western countries. Thus, gastric cancer is usually diagnosed at an advanced stage when patients

already have symptoms. This results in dismal prognosis and poor survival rates, emphasizing the necessity for innovative screening strategies. Recent studies have shown that upper gastro-intestinal lesions are significantly prevalent in patients with a positive fecal occult blood test, suggesting that upper endoscopies in patients that need a colonoscopy could be a promising strategy for gastric cancer screening. However, additional prospective data are required to confirm these results.

Study objective

The primary objective of the current protocol is the diagnostic value of a gastroscopy to detect gastric (pre)-neoplastic conditions in patients who need a colonoscopy as part of their clinical follow-up either after a positive screening test for colon cancer (FIT) or as part of polyp surveillance at Erasmus MC.
The secondary objectives include: i) The prevalence of other upper gastrointestinal conditions in the study population ii) The extra value of endoscopy to serology screening among other approaches. iii) The endoscopist*s performance to detect relevant gastric lesions, as well as oesophageal or duodenal conditions, and iv) Safety of the procedure and the participants* satisfaction, including also reasons not to participate.

Study design

This study is designed as a single center investigator initiated study in the Netherlands. This study is part of a larger multinational multicentre study which is funded through the Horizon Europe project TOGAS. The study will make use of prospective data collected in the specific context of this study. Furthermore biomaterial will be collected (e.g. blood, and biopsies).

Intervention

Patients will be asked to undergo an additional gastroscopy during their standard of care diagnostic endoscopy during which five biopsies will be taken. In addition, a blood sample (9 ml) will be taken at the day of endoscopy. In addition they will complete 1 questionnaire at the day of the endoscopies.

Study burden and risks

Patients will undergo an additional gastroscopy with Sydney protocol biopsies (five in total) taken in combination with their scheduled colonoscopy. Upper endoscopy is considered to be a safe procedure. the risks of a complication related to the gastroscopy are low (<0,10%), and mostly due to the sedation provided. However, all patients in this study will already undergo a colonoscopy with the same sedation, so additional sedation associated risks will not be applicable. Besides, although upper endoscopy is associated with

distress before and discomfort during the procedure, most patients do not experience it as painful, and it is reported to cause only a few symptoms afterward.
In addition to the gastroscopy, patients will undergo additional blood sampling using an existing cannula (9 ml), and they will be asked to fill in a feedback form at the day of the endoscopy. These additional procedures do not pose a significant risk or burden. There is a benefit for participants who test positive for H. Pylori infection based on the pathology report of the upper endoscopy. They will be offered eradication therapy with subsequent confirmation of treatment success. Benefit is also envisioned for participants with high-risk precancerous lesions based on the pathology report. They will be advised to undergo regular endoscopic surveillance as per international guidelines or direct treatment.

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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
• Patients without any known gastric condition who will undergo a colonoscopy after positive FIT screening or require a colonoscopy as part of polyp surveillance;
• Age 50-74;
• Able to undergo a gastroscopy;
• Capable of giving signed informed consent which includes compliance with the requirements and restrictions listed in the informed consent form (ICF) and in this protocol.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
• Previous esophageal or gastric surgery such as gastric bypass or esophagectomy.
• Patients with known GA/GIM, gastric cancer or treated in the past for gastric dysplasia with endoscopic therapy
• Patients with genetic cancer syndromes
• Acute upper GI bleeding within the last 4 weeks
• Patients with coagulation disorders leading to increased bleeding risk
• Pregnancy, breast-feeding women
• Patients with an insurmountable language barrier due to which it is impossible to perform correct and complete information about the purposes of the study.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-05-2024
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO Date:	29-04-2024
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	NL85535.078.23