Endoscopic staging and targeted biopsies for routine evaluation of precancerous gastric lesions

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27264

Source
Nationaal Trial Register

Brief title
ESTIMATE study

Health condition

gastric premalignant lesions, intestinal metaplasia
voorstadia maagkanker, intestinale metaplasie

Sponsors and support

Primary sponsor: Erasmus University Medical Center
Source(s) of monetary or material Support: Maag Lever Darm Stichting

Intervention

Outcome measures

Primary outcome

1. The diagnostic accuracy for the endoscopic diagnosis of intestinal metaplasia in Sydney biopsy locations

Secondary outcome

1. Reproducibility of endoscopic staging after expert review

2. Reproducibility of histopathology for detection of intestinal metaplasia

3. Number of dysplastic or neoplastic lesions detected

4. Longer inspection time of gastric mucosa increases accuracy

Study description

Background summary

Rationale

Although there has been a decline in the incidence of gastric adenocarcinoma, particularly in the Western world, it remains a major cause of cancer mortality. The key to having a significant impact on not only the prognosis of gastric cancer but also its global economic burden is to accurately identify the individuals at risk and intervene prior to them establishing gastric cancer through surveillance and existing efficacious therapies, including endoscopic resection. By embracing the significant improvements in endoscopic technology and changing the staging paradigm to an endoscopy led approach we will empower the endoscopist to risk stratify individuals with greater accuracy and decrease the already huge burden placed on our endoscopy and histopathology departments.

Objective

To evaluate the accuracy and reproducibility of enhanced endoscopic imaging for staging chronic atrophic gastritis.

Study design

Prospective evaluation of a diagnostic test

Study population

Patient already in surveillance for premalignant stomach lesions, or patients with new found lesions will be asked to participate in the current trial.

Intervention

Patients will be evaluated on separate occasions using standard white-light endoscopy plus random biopsies (current diagnostic strategy) and the using enhanced endoscopic imaging with targeted biopsies (proposed diagnostic strategy). We will compare both approaches using histopathology. Subsequently, a blood test will be drawn.

Study objective

Enhanced endoscopic imaging, including high-definition white light endoscopy and virtual chromoendoscopy, alongside targeted biopsies provides an accurate and reproducible assessment of chronic atrophic gastritis disease extent and staging, when compared to the current practice of white light endoscopy and random biopsies through the Sydney protocol biopsy strategy.

Study design

White light endoscopy with biopsies + serology samples at baseline

After 6 months narrow band imaging endoscopy with biopsies

Intervention

: Patients will be evaluated on separate occasions using standard white-light endoscopy plus random biopsies (current diagnostic strategy) and the using enhanced endoscopic imaging with targeted biopsies (proposed diagnostic strategy). We will compare both approaches using histopathology. Subsequently, a blood test will be drawn.

Contacts

Public
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Rotterdam
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Scientific
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Eligibility criteria

Inclusion criteria

1. All patients referred to the endoscopy department for an upper gastrointestinal endoscopy for investigation of symptoms, screening or surveillance, who are found to have chronic atrophic gastritis between November 2018 and May 2020.

2. Patients will be over the age of 18 years old.

3. Patients must be able to give informed consent.

Exclusion criteria

1. Patients with gastric neoplasia not amenable to endoscopic resection

2. Patient who do not have an indication for Sydney biopsy staging on standard WLE

3. Patients with significant comorbidities

4. Patients with coagulation disorders

5. Patients with previous gastric surgery

6. Being unable to complete the biopsy protocol on either endoscopy session

Study design

Design

Study type:	Interventional
Intervention model:	Factorial
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2019

Enrollment:	234
Type:	Anticipated

Ethics review

Positive opinion Date:	11-12-2018
Application type:	First submission

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
NTR-new	NL6389
NTR-old	NTR7661
Other	: MEC-2018-078

Study results