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

Gepubliceerd: 11-12-2018 Laatst bijgewerkt: 18-08-2022

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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27264

Bron
NTR

Verkorte titel
ESTIMATE study

Aandoening

gastric premalignant lesions, intestinal metaplasia
voorstadia maagkanker, intestinale metaplasie

Ondersteuning

Primaire sponsor: Erasmus University Medical Center
Overige ondersteuning: Maag Lever Darm Stichting

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

White light endoscopy with biopsies + serology samples at baseline

After 6 months narrow band imaging endoscopy with biopsies

Onderzoeksproduct en/of interventie

: 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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Factorieel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland Status:	Werving gestart
(Verwachte) startdatum:	01-01-2019
Aantal proefpersonen:	234

Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	11-12-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6389
NTR-old	NTR7661
Ander register	: MEC-2018-078

Resultaten