The identification and validation of risk factors to enable objective risk-stratification to predict malignant progression in Barrett’s Esophagus: a prospective multi-center study in community hospitals in the Amsterdam region

Gepubliceerd: 20-03-2020 Laatst bijgewerkt: 18-08-2022

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Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24029

Bron
NTR

Verkorte titel
Rebus-2

Aandoening

Barrett's esophagus; Barrett's related neoplasia

Ondersteuning

Primaire sponsor: Department of Gastroenteroogy and Hepatology, Amsterdam University Medical Centres (Amsterdam UMC)
Overige ondersteuning: Department of Gastroenteroogy and Hepatology, Amsterdam UMC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary Objective: To assess endoscopic and clinical risk factors for progression to high-grade dysplasia (HGD) or esophageal adenocarcinoma (EAC) in a large prospective cohort of BE patients from community hospitals aiding objective risk stratification.

Toelichting onderzoek

Achtergrond van het onderzoek

Endoscopic surveillance of patients with a Barrett's esophagus (BE) is crucial to detect neoplasia and its precursor lesions at a stage early enough to be curatively treated, if possible, even endoscopically. The effectiveness and efficiency of the current endoscopic surveillance is questionable as most of the data on risk factors was derived from tertiary care centers or from cohorts with limited surveillance time or surveillance quality. Improving risk-stratification would allow for better endoscopic surveillance. Patients could be stratified into a high-risk or a low-risk group so surveillance intervals can be tailored and the clinical and economic burden of endoscopic surveillance can be reduced.

Doel van het onderzoek

Patients could be stratified into a high-risk or a low-risk group so surveillance intervals can be tailored and the clinical and economic burden of endoscopic surveillance can be reduced.

Onderzoeksopzet

Planned surveillance endoscopies according to the Dutch guidelines for NDBE

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Aged between 18 and 75 years
- Endoscopic and histological evidence of NDBE (defined as intestinal metaplasia without dysplasia) with a circumferential extent of ≥2 cm and a total maximum extent of ≤10 cm
- Ability to provide a written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Visible lesions in the esophagus suspicious for neoplasia during the first endoscopy (according to the Paris classification)
- History of HGD or EAC in the esophagus
- Unfit for endoscopic surveillance or inability to obtain biopsies
- History of endoscopic or surgical treatment for esophageal dysplasia or EAC
- History of esophageal surgery other than fundoplication
- Presence of grade C or grade D erosive esophagitis (according to Los Angeles classification)
- Refusal or inability to provide written informed consent

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd

Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	10-05-2020
Aantal proefpersonen:	700
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
N/A

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL8474
Ander register	METC AMC : W20_154 # 20.192

Resultaten

Samenvatting resultaten
N/A