The WATS-EURO2 Pilot study

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Random biopsies are the current 'golden standard' in the surveillance of Barrett's esophagus. Random sampling is subjected to sampling error, because high grade dysplasia or esophageal adenocarcinoma's are highly focal. Since...

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

Samenvatting

ID

NL-OMON24680

Bron
NTR

Verkorte titel
The WATS-EURO2 Pilot study

Aandoening

Barrett esophagus

Ondersteuning

Primaire sponsor: None. Investigator initiated
Overige ondersteuning: AMC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Test the feasibility of the infrastructure, data collection, and the study database (in-cluding sending automatic e-mails, advising on surveillance intervals, reminding phy-sicians to schedule FU endsocopies, etc)
- To study the rate of HGD/EAC (biopsy diagnosed) in BE patients at high risk of progression

(i.e. after endoscopic removal of visible lesions containing HGD/EAC and/or a diagnosis of LGD) and in BE patients undergoing standard endoscopic surveillance.
- To study the concordance/discordance between random biopsies and WATS brushing collected at the baseline endoscopy and at follow-up endoscopies for the diagnosis HGD/EAC.
- To study the rate of progression to HGD/EAC in endoscopic biopsies (targeted or random) or endoscopic resection specimens during follow-up, after a baseline WATS-positive-biopsy negative diagnosis for HGD/EAC.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:
Patients with BE are kept under endoscopic surveillance, since early detection of esophageal adenocarcinoma (EAC) significantly improves the prognosis compared to late detection. Current endoscopic surveillance strategies rely on random sampling, which is time-consuming and has an inevitable risk for significant sampling error. The WATS-3D brush samples a much wider area of the esophageal epithelium, and prior studies have suggested that it detects more dysplasia. However, the clinical value of these WATS-positive-biopsy-negative cases is unknown. We aim to study the rate of developing a biopsy-based diagnosis of HGD/EAC in Barrett's patients at high risk of progression (i.e. after endoscopic removal of visible lesions containing HGD/EAC and/or a diagnosis of LGD) as well as in patients in a standard Barrett's surveillance program. In these patients we will combine biopsy sampling with WATS brushing at baseline and all follow-up endoscopies. This will allow us to study the natural history of WATS-positive-biopsy-negative case and of WATS-specific outcomes such as Basal-crypt dysplasia.

Objective:
To study the rate of HGD/EAC (biopsy diagnosed) in BE patients at high risk of progression (i.e. after endoscopic removal of visible lesions containing HGD/EAC and/or a diagnosis of LGD) and in BE patients undergoing standard endoscopic surveillance, and to study the concordance/discordance between random biopsies and WATS brushing collected at the baseline endoscopy and at follow-up endoscopies for the diagnosis HGD/EAC.
Study design: This is an multi center, prospective, tandem arm trial in 3 centers with a tertiary referral function for detection and treatment of early Barrett's neoplasia

Doel van het onderzoek

Random biopsies are the current 'golden standard' in the surveillance of Barrett's esophagus. Random sampling is subjected to sampling error, because high grade dysplasia or esophageal adenocarcinoma's are highly focal. Since WATS-3D brushes sample a larger area of the Barrett-esophagus, it seems logical that it would detect more dysplasia.

Onderzoeksopzet

NA

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients age: ≥ 18 years
- Willingness to undergo both WATS and random forceps biopsies while undergoing conventional EGD with sedation
- Ability to provide written, informed consent (approved by IRB and (biobank committee)) and understand the responsibilities of trial participation
- BE with a circumferential extent of ≥2cm, or a maximum extent of ≥4cm, and a total maximum extent of ≤10cm (in case of prior ER: BE length after ER)
- Cohort 1: Patients referred for work-up of LGD, HGD or low-risk cancer (m1 to sm1, with-out lympho-vascular invasion and poor differentiation), either diagnosed in random biop-sies or in prior endoscopic resection specimen
- Cohort 2: Patients with known BE enrolled in endoscopic surveillance programs

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients with visible lesions according to the Paris classification at the time of the WATS and

random biopsy testing (prior endoscopic resection is allowed)
- Patients with high-risk cancer after endoscopic resection: either sm2/3 invasion, poor differentiation, lympho-vascular invasion, or R1 vertical resection margin
- Patients within six weeks of receiving targeted forceps biopsies and/or ER
- History of esophageal or gastric surgery other than Nissen fundoplication
- History of esophageal ablation therapy
- Coagulopathy with INR >2.0, thrombocytopenia with platelet counts < 50,000
- Subject has a known history of unresolved drug or alcohol dependency that would limit ability to comprehend or follow instructions related to informed consent, post-treatment instructions, or follow-up guidelines

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2020
Aantal proefpersonen:	90
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 54901
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8216
CCMO	NL71034.018.19
OMON	NL-OMON54901

Resultaten