The WATS-EURO2 Pilot study

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24680

Source
NTR

Brief title
The WATS-EURO2 Pilot study

Health condition

Barrett esophagus

Sponsors and support

Primary sponsor: None. Investigator initiated
Source(s) of monetary or material Support: AMC

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

To study the concordance/discordance between random biopsies and WATS brushing collected at the baseline endoscopy and at follow-up endoscopies for the diagnosis intestinal metaplasia.
- To study the rate of diagnosing intestinal metaplasia in endoscopic biopsies during follow-up, after a baseline WATS-positive-biopsy-negative diagnosis for intestinal metaplasia.
To evaluate the rate of progression to HGD/EAC in endoscopic biopsies (targeted or random) or endoscopic resection specimens during follow-up, after a baseline diagnosis WATS3D brush crypt dysplasia diagnosis.
- To assess whether a positive finding of HGD/EAC using the WATS system is reproducible on subsequent endoscopies.

Study description

Background summary

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

Study objective

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.

Study design

NA

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2020
Enrollment:	90
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Not applicable
Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 54901
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results