Wide Area Transepithelial sample Esophageal Biopsy combined with Computer assisted 3-Dimensial Tissue Analysis (WATS) for the detection of High Grade Esophageal Dysplasia and Adenocarcinoma: A multicenter prospective, randomized, tandem study

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To evaluate the utility of the WATS system, as a potential substitute for the random sampling method that is currently recommended as an adjunct to targeted biopsy

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational invasive

Summary

ID

NL-OMON46641

Source
ToetsingOnline

Brief title
WATS European 810 trial 2017

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms malignant and unspecified

Synonym
Barrett's dysplasia

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,CDx Diagnostics

Intervention

Keyword: Barrett□s Dysplasia, Barrett□s Early cancer, Diagnosis, WATS Biopsy

Outcome measures

Primary outcome

The detection rate of Barrett*s associated HGD and EAC using WATS and random 4

quadrants/2cm biopsies

Secondary outcome

The effect of order of sampling on the outcome.

Study description

Background summary

Esophageal adenocarcinoma (EAC) is a disease with a poor prognosis at advanced stage. It is clear that identifying esophageal adenocarcinoma at an early and treatable stage reduces morbidity and mortality. The incidence of Barrett*s esophagus (BE) and associated EAC highly increased in the last years. Adequate monitoring strategies and improved diagnostic procedures are therefore essential.
The current systemic four-quadrant biopsy at 2-cm intervals of the dysplastic and non-dysplastic BE segment leaves the majority of the BE epithelium undiagnosed. Sampling BE cells with cytology brushes has been considered to increase the sensitivity for dysplasia and EC. The limiting factors are the superficial sampling and the difficulty of the analysis of the thick tissue smear by a two-dimensional cytology microscope.
The WATS system (developed by CDx Diagnostics) consists of a trans-epithelial cytology brush designed to sample cells from all three layers of the epithelium and the diagnosis of the brush specimen by advanced computer image analysis system at CDx Diagnostics. In this study, we will compare the

sensitivity of the WATS system with the random sampling method by randomization of the order of sampling during an imaging endoscopy

Study objective

To evaluate the utility of the WATS system, as a potential substitute for the random sampling method that is currently recommended as an adjunct to targeted biopsy

Study design

This is an international, multi-center, prospective, randomized, tandem trial

Intervention

During the surveillance endoscopy eligible patients will be randomized to one of the two arms of the study. Patients will undergo random 4 quadrant mucosal biopsies every 2cm followed by WATS brushing of the BE segment (arm 1) or WATS brushing followed by random 4 quadrant mucosal biopsies (arm 2).

Study burden and risks

The WATS biopsy will be done during an imaging endoscopy scheduled according current guidelines. The amount of random biopsies during this endoscopy is as in the current guidelines. The risks associated with upper endoscopy and WATS are the same as those associated with upper endoscopy and routine forceps biopsy. These risks and discomforts are associated with sedation and endoscopy with forceps biopsy itself (small amounts of bleeding, sore throat)
The minimal increase in time needed to obtain WATS samples will not add significant risk to and will not require additional exposure to sedation.
Participation will not influence the treatment of the disease. The outcome of the routine random biopsies only will be the guideline for further ablative therapy or surveillance.
There is no direct benefit from taking part in this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Patients age: * 18 years
* Patients should have a history of Barrett*s associated esophageal neoplasia (either low or high-grade dysplasia on biopsy without visible lesions or well to moderately differentiated mucosal adenocarcinoma, without lymphovascular invasion after EMR) confirmed on histology
* 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 understand the responsibilities of trial participation
* Only patients without visible lesions at the time that they undergo both random forceps biopsies and WATS testing of the esophagus will be included in this study

Exclusion criteria

* BE length < 2 cm circumferential extent or > 10 cm total extent
* Patients within six weeks of receiving targeted forceps biopsies and/or EMR
* Patients with visible mucosal lesion according to the Paris classification at the time of the WATS and random biopsy testing
* Patients with visible lesions that are either submucosal or covered with a clinically intact epithelium
* History of esophageal or gastric surgery other than Endoscopic Mucosal Resection (EMR),

except for Nissen fundoplication
* Patients who have already undergone endoscopic ablative therapies
* Coagulopathy with INR >2.0, thrombocytopenia with platelet counts < 50,000
* The subject is pregnant or planning a pregnancy during the study period
* 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 invasive
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-03-2018
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	WATS 3D system
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	06-03-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO Date:	14-08-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
ClinicalTrials.gov	NCT03015389
CCMO	NL62816.018.17