The ARGOS project: Real-time assessment of Barrett neoplasia using computer aided detection. A pilot study

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The aim of this pilot study is to interrogate the feasibility of the workflow, using this image-based CAD system real-time in the endoscopy suite.

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

Summary

ID

NL-OMON48041

Source
ToetsingOnline

Brief title
ARGOS project

Condition

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

Synonym
Esophageal Adenocarcinoma, esophageal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: KWF-STW

Intervention

Keyword: Barrett Esophagus, Computer Aided Detection, Endoscopy, Esophageal adenocarcinoma

Outcome measures

Primary outcome

1) To evaluate feasibility of the workflow of using a real-time, image-based

CAD system in the endoscopy suite.

2) To assess the preliminary diagnostic accuracy of the CAD system for

real-time detection of Barrett neoplasia.

Secondary outcome

n.a.

Study description

Background summary

Barrett*s Esophagus (BE) is a known precursor for esophageal adenocarcinoma (EAC). BE patients undergo regular endoscopic surveillance by general endoscopists to detect EAC at an early stage. However, endoscopic detection of early neoplasia is difficult and early lesions are therefore often missed. Primarily, this is due to its subtle appearance.

The ability of modern-day computers to automatically recognize informative patterns in data sets can potentially improve endoscopic detection of early neoplastic BE. Recently, a CAD system has been developed by the consortium that can automatically detect and localize early neoplastic Barrett lesions on endoscopic WLE images with high accuracy.

Study objective

The aim of this pilot study is to interrogate the feasibility of the workflow, using this image-based CAD system real-time in the endoscopy suite.

Study design

Multicenter pilot study in which the feasibility of usage of a computer aided detection system will be evaluated.

Study burden and risks

The endoscopic procedure will be performed according to standard practice. For this study, only the use of the computer aided detection system is additional. This is safe and poses no extra risks for patients.

The computer aided detection system will work separately and independantly from the standard endoscopic equipment, since it only outputs the video signal to an external system on a stand-alone computer with its own monitor. On this monitor, any visual abnormalities will be displayed, that the endoscopist can then interrogate using the standard endoscopic equipment.

Therefore there is no in-vivo use of a medical device and there are nor additional risks for the patient.

The computer aided detection system will never make a clinical decision: The endoscopist will always decide whether to act or not. The endoscopic procedure will take 5-10 minutes longer, due to the collection of additional imagery.

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

- Minimum age 18 years;
- Patients with NDBE referred for endoscopic surveillance, or patients referred for endoscopic work-up of HGD or EAC likely to require endoscopic resection (EMR or ESD);
- Signed informed consent.

Exclusion criteria

- Prior history of surgical or endoscopic treatment for oesophageal neoplasia;
- Presence of erosive esophagitis (Los Angeles classification *A);
- Inability to undergo EMR/ESD and/or obtain biopsies (e.g. due to anticoagulation, coagulation disorders, varices).

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2019
Enrollment:	23
Type:	Actual

Ethics review

Approved WMO Date:	08-02-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-06-2019
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
CCMO	NL68425.018.18