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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28965

Source
Nationaal Trial Register

Brief title
ARGOS pilot study

Health condition

Barrett Esophagus, Barrett neoplasia

Sponsors and support

Primary sponsor: Amsterdam University Medical Centers, location AMC
Source(s) of monetary or material Support: This study is sponsored by KWF-STW as part of their programm 'Technology for Oncology'

Intervention

Outcome measures

Primary outcome

To evaluate feasibility of the workflow of using a re al-time, image-based CAD system in the endoscopy suite.

Secondary outcome

To assess the preliminary diagnostic accuracy of the CAD system for real-time detection of Barrett neoplasia.

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 our group that can automatically detect and
localize early neoplastic Barrett lesions on endoscopic WLE images with high accuracy. The aim of this pilot study is to interrogate the feasibility of the endoscopic workflow, using this image-based CAD system real-time in the
endoscopy suite.

Study objective

The use of an-image based CAD system is feasible and enables endoscopic detection of Barrett neoplasia

Study design

Outcome measures apply to the endoscopic procedure. No further time point apply to this study.

Contacts

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Eligibility criteria

Inclusion criteria

- 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
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	01-03-2019
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion Date:	18-02-2019
Application type:	First submission

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
NTR-new	NL7544
Other	MEC Amsterdam University Medical Centers, Location AMC : METC 2018_334

Study results