A Comparison of Blue Light Imaging (BLI), Linked Color Imaging (LCI) and White Light Endoscopy (WLE) in Patients with Barrett’s neoplasia

No registrations found.

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

Summary

ID

NL-OMON23557

Source
Nationaal Trial Register

Brief title
Barrett BLI-LCI study

Health condition

Barrett's neoplasia

Sponsors and support

Primary sponsor: FUJIFILM Europe
Source(s) of monetary or material Support: FUJIFILM Europe

Intervention

Outcome measures

Primary outcome

Delineation scores:
a) Percentage of the ground truth delineation delineated;
b) AND/OR score for the ground truth delineation;
c) Difference in delineation scores for different levels of endoscopic experience;

VAS- and ordinal scores for assessment per lesion:
a) Characterization (Paris classification and surface relief);
b) Delineation;
c) Difference in scores for different levels of endoscopic experience;

Secondary outcome

See above

Study description

Background summary

A recent study performed by our group showed additional value for BLI for the visualization of BE neoplasia, when assessed by experts. Experts appreciated BLI better than WLE for visualization and delineation of BE neoplasia. Furthermore, their quantitative agreement increased significantly when BLI was offered next to WLE for lesions that were hard to delineate with WLE alone.
The aim of this study is to evaluate BLI and LCI as an additional tool next to WLE for the use of visualization and delineation of early Barrett neoplasia, when used by endoscopists with different levels of endoscopic expertise.

Study objective

Blue Light Imaging (BLI) and Linked Color Imaging (LCI) have additional value for the visualization of Barrett's neoplasia, when compared to White Light Endoscopy (WLE).

Study design

This study is divided in 4 separate assessment phases, in which the endoscopic images will be scored and delineated by the assessors. Each phase is separated by a wash-out period of 2 weeks.
Phase 1: Only WLE images are shown (n=30)
Phase 2: WLE and BLI images are shown (n=15), WLE and LCI images are shown (n=15)
Phase 3: WLE and LCI images are shown (n=15), WLE and BLI images are shown (n=15)
Phase 4: WLE, BLI and LCI images are shown (n=30)

Intervention

n.a.

Contacts

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Eligibility criteria

Inclusion criteria

Data from our previous study will be used (doi: 10.1016/j.gie.2018.10.046.). No new patient data will be collected.
A group of 90 international endoscopist assessors (30 fellows, 30 junior GE, 30 senior GE) will assess the endoscopic images collected in the previous study.

Exclusion criteria

Data from our previous study will be used (doi: 10.1016/j.gie.2018.10.046.). No new patient data will be collected.
A group of 90 international endoscopist assessors (30 fellows, 30 junior GE, 30 senior GE) will assess the endoscopic images collected in the previous study.

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:	Other
Start date (anticipated):	01-10-2018
Enrollment:	30
Type:	Unknown

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

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7541
Other	METC AMC : W15_068

Study results