

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

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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).

Ethische beoordeling	Niet van toepassing
Status	Anders
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23557

Bron

Nationaal Trial Register

Verkorte titel

Barrett BLI-LCI study

Aandoening

Barrett's neoplasia

Ondersteuning

Primaire sponsor: FUJIFILM Europe

Overige ondersteuning: FUJIFILM Europe

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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;

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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).

Onderzoeksopzet

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)

Onderzoeksproduct en/of interventie

n.a.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Anders
(Verwachte) startdatum:	01-10-2018
Aantal proefpersonen:	30
Type:	Onbekend

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Niet van toepassing	
Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7541
Ander register	METC AMC : W15_068

Resultaten