

# Blue light imaging has an additional value to white light endoscopy in visualization of early Barrett's neoplasia: an international multicenter cohort study

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<b>Registration date</b> 19/02/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 04/10/2022	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Esophageal cancer (adenocarcinoma; EAC) is cancer that starts in the esophagus - the food pipe that runs between the throat and the stomach. EAC is amongst the deadliest cancers, with 5-year survival rates of less than 15%. The incidence of esophageal cancer has risen rapidly over the last decades. Patients with a condition called Barrett's Esophagus (BE) are at increased risk of developing EAC. In BE the normal lining of the esophagus changes to tissue that resembles the lining of the intestine. BE is caused by gastrointestinal acid reflux (where stomach acid travels up towards the throat). EAC develops through a stepwise process from BE to low-grade and high-grade dysplasia, and eventually to EAC. Therefore, the standard of care for Barrett's patients consists of regular endoscopies with white-light endoscopy (WLE) and biopsies (tissues samples) to detect EAC at an early stage. When detected at an early stage, patients with EAC can be treated endoscopically with an excellent prognosis. However, EAC in BE patients is difficult to distinguish with WLE alone. Blue Light Imaging (BLI) is a new endoscopic imaging technique that uses the excitation of blue light to improve detection of EAC in BE patients. The BLI technique is incorporated in the newest FUJIFILM endoscopy systems, as well as WLE. The aim of this study is to find out whether BLI improves detection of BE before endoscopic resection (a procedure to remove the abnormal tissue).

### Who can participate?

Patients aged over 18 with BE referred for endoscopy and likely to require endoscopic resection

### What does the study involve?

During endoscopy, corresponding WLE and BLI endoscopic images are collected. After the procedure, these images are stored in a database and examined by six international experts.

### What are the possible benefits and risks of participating?

The results of this study might in future improve endoscopy for BE patients with EAC. There are no extra risks of participation.

Where is the study run from?

1. Academic Medical Center (Netherlands)
2. Catharina Hospital Eindhoven (Netherlands)
3. University Hospital Leuven (Belgium)

When is the study starting and how long is it expected to run for?

January 2015 to January 2018

Who is funding the study?

1. FUJIFILM Europe
2. Academic Medical Center (Netherlands)

Who is the main contact?

Jeroen de Groof

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## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

## Study information

### Scientific Title

Blue light imaging has an additional value to white light endoscopy in visualization of early Barrett's neoplasia: an international multicenter cohort study

### Acronym

BLI study

### Study objectives

Blue Light Imaging (BLI) has additional value in overview and in magnification for the use of characterization and delineation of early neoplastic Barrett's lesions compared to White Light Endoscopy (WLE).

### Ethics approval required

Old ethics approval format

### **Ethics approval(s)**

The Medical Research Involving Human Subjects Act did not apply to this study. Official approval of this study was therefore waived by the Medical Ethics Review Committees of all participating centers (AMC Amsterdam, Catharina Hospital Eindhoven, University Hospital Leuven)

### **Study design**

Multicenter prospective cohort study

### **Primary study design**

Observational

### **Study type(s)**

Diagnostic

### **Health condition(s) or problem(s) studied**

Barrett's neoplasia

### **Interventions**

Multiple corresponding overview- and magnification WLE and BLI endoscopic images of BE neoplasia are collected. Subsequently these images are scored and delineated by six international experts using an proprietary online module.

### **Intervention Type**

Device

### **Primary outcome(s)**

1. Experts' appreciation of macroscopic appearance and surface relief, measured using VAS scores in the first two assessment phases, each separated by a wash-out period of 2 weeks: Phase 1: WLE images only; Phase 2: BLI images only
2. Experts' ability to delineate the lesion, measured using VAS scores in the first two assessment phases, each separated by a wash-out period of 2 weeks: Phase 1: WLE images only; Phase 2: BLI images only
3. Experts' preferred technique for macroscopic appearance + surface relief and preferred technique for delineation, measured using ordinal scores in assessment phase 3 (WLE+BLI images), separated from the second assessment phase with a wash-out period of two weeks

### **Key secondary outcome(s)**

Experts' quantitative agreement on lesion delineations, measured using AND/OR scores in all three separate assessment phases, each separated by a wash-out period of 2 weeks: Phase 1: WLE images only; Phase 2: BLI images only; Phase 3: WLE+BLI images

### **Completion date**

01/01/2018

## **Eligibility**

### **Key inclusion criteria**

1. Age > 18 years
2. Patients with BE referred for endoscopic work-up of HGD or EAC likely to require endoscopic resection (EMR or ESD)
3. Lesions can be completely visualized in a single endoscopic image in overview
4. Lesions in which a type 0-II lesion is the dominant part (the more subtle lesions)
5. Eligible for EMR or ESD
6. Signed informed consent

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

40

**Key exclusion criteria**

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

**Date of first enrolment**

04/09/2015

**Date of final enrolment**

07/06/2017

**Locations****Countries of recruitment**

Belgium

Netherlands

**Study participating centre**

Academic Medical Center Amsterdam

Meibergdreef 9

Amsterdam  
Netherlands  
1105 AZ

**Study participating centre**  
**Catharina Hospital Eindhoven**  
Michelangelolaan 2  
Eindhoven  
Netherlands  
5623 EJ

**Study participating centre**  
**University Hospital Leuven**  
Herestraat 49  
Leuven  
Belgium  
3000 Leuven

## Sponsor information

**Organisation**  
Academic Medical Center Amsterdam

## Funder(s)

**Funder type**  
Industry

**Funder Name**  
FUJIFILM Europe

**Funder Name**  
Academisch Medisch Centrum

**Alternative Name(s)**  
Academic Medical Center, AMC

**Funding Body Type**

Private sector organisation

### Funding Body Subtype

Universities (academic only)

### Location

Netherlands

## Results and Publications

### Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

### IPD sharing plan summary

Data sharing statement to be made available at a later date

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/04/2019	23/11/2020	Yes	No
<a href="#">Protocol file</a>			04/10/2022	No	No