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

Submission date
15/02/2018

Recruitment status
No longer recruiting

Registration date
19/02/2018

Overall study status
Completed

Last Edited
04/10/2022

Condition category
Digestive System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
01/01/2015

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

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 ≥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

Sponsor details

Meibergdreef 9
Amsterdam
Netherlands
1105 AZ

Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
Study protocol and statistical analyses will not be made available. Planned publication of the results in a high-impact peer reviewed journal.

Intention to publish date
01/04/2018

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?
Results article	results	01/04/2019	23/11/2020	Yes	No
Protocol file			04/10/2022	No	No