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Comparing two colonoscopy imaging techniques to detect precancerous changes in patients with inflammatory bowel disease

Submission date 03/03/2026	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 09/03/2026	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 09/03/2026	**Condition category** Digestive System	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
Patients with long-standing inflammatory bowel disease (IBD), such as ulcerative colitis or Crohn's disease affecting the colon, have a higher risk of developing bowel cancer over time. To reduce this risk, patients undergo regular surveillance colonoscopies to look for early warning signs of cancer, known as dysplasia. One way to improve detection is to spray a blue dye (methylene blue) onto the bowel lining during the procedure, which helps highlight abnormal areas. Another approach uses special lighting built into the camera to enhance the appearance of the bowel surface electronically, without the need for dye. On the Fujifilm camera system, these lighting modes are called blue light imaging (BLI) and linked color imaging (LCI). The aim of this study is to compare these two techniques directly to find out which one detects more dysplasia during surveillance colonoscopy in IBD patients.

Who can participate?
Adults aged 18 years and over with a diagnosis of ulcerative colitis or Crohn's disease affecting the colon, who are due for a routine surveillance colonoscopy. Participants must have had their bowel condition for at least 8 years or have known risk factors for bowel cancer such as primary sclerosing cholangitis, extensive colitis, or a previous finding of dysplasia.

What does the study involve?
Participants are randomly assigned to one of two groups. In one group, the endoscopist sprays methylene blue dye onto the bowel lining during the colonoscopy. In the other group, the endoscopist uses the camera's built-in electronic lighting modes (BLI and LCI) to examine the bowel without any dye. In both groups, any suspicious areas are biopsied and sent to the laboratory. Additional random biopsies are also taken from normal-looking areas every 10 cm, as recommended by international guidelines. The pathologists examining the tissue samples do not know which technique was used.

What are the possible benefits and risks of participating?
Participants receive a thorough surveillance colonoscopy using an established technique for detecting dysplasia. There is no additional risk beyond those of a standard surveillance

colonoscopy, as both methods are already used in routine clinical practice. The risks of colonoscopy in general include a small chance of bleeding or perforation, but these are rare.

Where is the study run from?
Al Adan Hospital, Ministry of Health (Kuwait)

When is the study starting and how long is it expected to run for?
January 2023 to December 2025

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Study information

Scientific Title
A prospective randomized controlled study comparing methylene blue dye-based chromoendoscopy versus Fujifilm virtual chromoendoscopy (BLI/LCI) for dysplasia detection in patients with inflammatory bowel disease

Acronym
IBD-DYS

Study objectives
To compare the per-patient dysplasia detection rate between methylene blue dye-based chromoendoscopy and Fujifilm virtual chromoendoscopy (BLI/LCI) in patients undergoing surveillance colonoscopy for inflammatory bowel disease.

Ethics approval required
Ethics approval required

Ethics approval(s)
submitted 02/03/2026, Kuwait Ministry of Health Research Ethics Committee (Ministry of Health Research Ethics Committee, Kuwait City, 13110, Kuwait; +965 (0)90069869; hkhamis@moh.gov.kw), ref: 020320266932

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Diagnostic

Study type(s)

Health condition(s) or problem(s) studied
Inflammatory bowel disease (ulcerative colitis and Crohn’s colitis)

Interventions
Randomisation was performed using a computer-generated random sequence with permuted block randomisation (block sizes of 4 and 6, randomly varied). Allocation was concealed using sequentially numbered, sealed opaque envelopes, prepared by an independent research coordinator not involved in patient recruitment or endoscopic procedures. Envelopes were opened immediately before each procedure by the attending nurse, and the endoscopist was informed of the allocated surveillance modality at that time.

Participants are randomized 1:1 to undergo surveillance colonoscopy using either:
1. Methylene blue dye-based chromoendoscopy (0.1% solution applied segmentally during withdrawal), or
2. Fujifilm ELUXEO virtual chromoendoscopy using blue light imaging (BLI) and/or linked color imaging (LCI) without dye application.
All visible lesions are biopsied, with additional random biopsies obtained every 10 cm according to SCENIC recommendations.

Intervention Type
Procedure/Surgery

Primary outcome(s)

1. Per-patient dysplasia detection rate measured using the proportion of patients with at least one histologically confirmed dysplastic lesion detected at index surveillance colonoscopy procedure

Key secondary outcome(s))
1. Dysplastic lesion morphology and anatomical distribution measured using the number and percentage of flat versus polypoid lesions and right versus left colon location at colonoscopy procedure

2. Withdrawal time and total procedure time measured using the mean withdrawal time (minutes) at during procedure

3. Independent clinical predictors of dysplasia detection measured using the adjusted odds ratios from multivariable logistic regression at analysis after completion of recruitment

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Adults ≥18 years
2. Confirmed diagnosis of ulcerative colitis or Crohn’s colitis
3. Disease duration ≥8 years, or any duration with high-risk features (primary sclerosing cholangitis [PSC], extensive colitis, prior dysplasia)
4. Scheduled for elective surveillance colonoscopy
5. Able to provide informed consent

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
75 years

Sex
All

Total final enrolment
300

Key exclusion criteria
1. Known colorectal cancer
2. Prior colectomy
3. Severe active colitis requiring urgent intervention

4. Inadequate bowel preparation
5. Pregnancy
6. Inability to provide informed consent

Date of first enrolment
01/01/2023

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
Kuwait

Sponsor information

Organisation
Ministry of Health

ROR
https://ror.org/036njfn21

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available