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Future of real time endoscopy, artificial intelligence

Submission date	**Recruitment status**	[_] Prospectively registered
23/02/2024	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/02/2024	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
23/02/2024	Cancer	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
This study is a substudy of the CONSCOP2 study (https://www.isrctn.com/ISRCTN98539180). Odin Medical has developed a Computer Assisted Detection and Diagnosis system for colonoscopy. The system acts like a second pair of eyes during the procedure using artificial intelligence (AI) to find/analyse polyps in colonoscopy images.
The AI solution works with existing hospital equipment. It sends the colonoscopy image from the hospital to a secure cloud/super-computer where they are analysed.
The aim of this project is to demonstrate the benefits of using AI in colonoscopy through a multicentre randomised controlled trial. These benefits include, better patient outcomes by improving polyp/cancer detection rates, improved patient experience with instant diagnosis and increased operational efficiency. The project will gather clinical data and perform health economic analyses.

Who can participate?
CONSCOP2 participants will be approached for additional optional consent to participate in the FORE-AI sub-study.

What does the study involve?
Participants will have the colonoscopy as usual, however some will be analysed using AI, and others by the colonoscopist, in order to evaluate AI performance. This will not affect the standard care of the participants in any way.

What are the possible benefits and risks of participating?
By participating in bowel screening, all participants will already have taken steps to detect polyps and consequently reduce their risk for future bowel cancer. If allocated to the dye spray group, more polyps may be detected and removed that could have turned into cancer, which further minimises the risk of future bowel cancer. However, the colonoscopy with dye spray will take on average 6 minutes longer than usual, especially if extra polyps are found, and there may be an increased risk of complications (e.g. bleeding if polyps found are removed) although we believe this to be very unlikely. Additionally, there is the chance that the extra polyps remove may never have turned into cancer.
For all participants, the main benefits of the study will be to inform UK bowel cancer screening

programmes in the future as to whether the using dye spray during colonoscopies helps in the detection of serrated polyps and possibly prevention of bowel cancers.
The blue dye used within the interventional arm is a safe food colouring agent and is already used routinely in various endoscopy procedures in standard clinical practice. Extremely rarely there may be individuals with a specific allergic response to this in the past. For this reason, anyone with a known allergy to a food colouring agent will be excluded from taking part in the study.

Where is the study run from?
The trial team are based in the Centre for Trials Research (CTR) at Cardiff University. Overall, the researchers plan that 25 centres in total across Wales, England and Scotland will participate in the recruitment for the trial. The lead centre will be Llandough Hospital (Cardiff & Vale University Health Board) as this is the site where the Chief Investigator, Dr Sunil Dolwani, is based.

When is the study starting and how long is it expected to run for?
June 2021 to July 2023

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Georgina Gardner
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
271876

Protocol serial number
SPON 1781-19

Study information

Scientific Title
Future of Real Time Endoscopy, Artificial Intelligence (substudy of CONSCOP2)

Acronym
FORE AI

Study objectives
FORE AI is a separately funded study that will be conducted on a subset of CONSCOP2 (https://www.isrctn.com/ISRCTN98539180) participants. The project is led by Odin Vision a trading name of Odin Medical Limited and will be conducted in collaboration with the CONSCOP2 trial team, Cardiff University Division of Population Medicine, CTR, Aquarius Population Health, and the Bowel and Cancer Research Charity. The study will investigate the use of artificial intelligence to analyse real time colonoscopy videos during screening colonoscopy as part of the bowel cancer screening program in sites throughout England and Wales to improve the detection of and diagnosis of polyps. This will collect prospective video data only and will not affect the standard care of the participants in any way.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 18/01/2021, Wales REC6 (c/o Public Health Wales Building 1 Jobswell Road St David's Park, Swansea, SA31 3HB, United Kingdom; +44 1267 61 1164; Wales.REC6@wales.nhs.uk), ref: 20/WA/0019

Primary study design
Observational

Study design
Observational randomised controlled

Study type(s)
Diagnostic, Screening, Efficacy

Health condition(s) or problem(s) studied
Bowel/colorectal cancer

Interventions
The CADDIE system will be deployed to collect video and histopathology data from patients randomised to high-definition white light colonoscopy with or without Indigo Carmine dye spray and with AI (colonoscopists all high detectors and blinded to AI results at the time of the procedure) (part of the CONSCOP2 study https://www.isrctn.com/ISRCTN98539180). The results

from the AI annotated group will be compared to the colonoscopist detection and with histopathology.

During a standard colonoscopy procedure, the colonoscope transmits video data to a monitor for the attending physician's examination, aiming to identify polyps in the patient's colon. Permission is sought from the individual to utilize a recording of this video in real time for the purpose of advancing new technological developments. It is emphasised that this request does not impact the colonoscopy procedure itself. The goal is to enhance future technology that can assist doctors in more accurately detecting polyps and providing instant diagnoses. Any polyps removed during the colonoscopy are forwarded to a pathologist for diagnosis

Intervention Type
Procedure/Surgery

Primary outcome(s)
Detection and diagnosis of polyps using a video of the procedure will be compared between the AI software and the colonoscopists to assess the accuracy of the AI.

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
07/07/2023

Eligibility

Key inclusion criteria
In the participating FORE AI sites, all CONSCOP2 (https://www.isrctn.com/ISRCTN98539180) participants will be approached for additional optional consent to participate in the FORE-AI sub-study via the CONSCOP2 main PIS/ICF.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
56 Years

Upper age limit
74 Years

Sex
All

Total final enrolment

1002

Key exclusion criteria
1. Previous resectional colorectal surgery (as this would influence both study methods and outcomes depending on the length of residual colon in the individual)
2. Any participants not deemed fit for colonoscopy on the screening program or undergoing alternative investigation such as CT pneumocolon or minimal prep CT scan as their index procedure instead.
3. Known allergy to food colouring agent (as the Indigo Carmine dye is a safe food colouring agent but extremely rarely there may be individuals with a specific allergic response to this in the past).
4. Previous inclusion in trial

Date of first enrolment
23/07/2021

Date of final enrolment
07/07/2023

Locations

Countries of recruitment
United Kingdom

England

Wales

Study participating centre
Betsi Cadwaladr University Lhb
Executive Offices, Ysbyty Gwynedd
Penrhosgarnedd
Bangor
United Kingdom
LL57 2PW

Study participating centre
Hywel Dda University Lhb
Corporate Offices, Ystwyth Building
Hafan Derwen
St Davids Park, Jobswell Road
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United Kingdom
SA31 3BB

Study participating centre
Cardiff & Vale University Lhb
Woodland House
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Study participating centre
CWM TAF UNIVERSITY LHB
CWM TAF UNIVERSITY LHB,
DEWI SANT HOSPITAL,
ALBERT ROAD,
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CF37 1LB
Pontypridd
United Kingdom
CF37 1LB

Study participating centre
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
University Hospitals of Leicester NHS Trust
Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Study participating centre
Gloucestershire Hospitals NHS Foundation Trust
Cheltenham General Hospital
Sandford Road
Cheltenham
United Kingdom
GL53 7AN

Study participating centre
Bradford Teaching Hospitals NHS Foundation Trust
Bradford Royal Infirmary
Duckworth Lane
Bradford
United Kingdom
BD9 6RJ

Sponsor information

Organisation
Cardiff University

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research Applied Research Collaboration East of England

Alternative Name(s)
Applied Research Collaboration East of England, NIHR ARC East of England, ARC East of England, NIHR Applied Research Collaboration East of England, NIHR Applied Research Collaboration (ARC) North East, National Institute for Health Research (NIHR) Applied Research Collaboration (ARC), ARC EoE, NIHR ARC EoE

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be 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?
Participant information sheet	version 1	17/11/2020	23/02/2024	No	Yes
Protocol file	version 4	17/11/2020	23/02/2024	No	No