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ColoVision: Using computers to instantly find and describe colorectal polyps

Submission date	Recruitment status	[_] Prospectively registered
30/01/2023	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
31/08/2023	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
31/08/2023	Digestive System	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Colorectal cancer is a major health problem. Most colorectal cancers develop from precursor lesions (polyps), and early detection and removal of these polyps can reduce rate and improve outcome of colorectal cancer.

Colonoscopy is the gold standard test to detect and remove polyps, however it has some limitations including a significant polyp miss rate.

Computer aided detection (CADe) and diagnosis (CADx) of polyps is rapidly progressing and recent studies have shown promising results. However, there is still lack of high-quality data from well-designed and implemented randomised trials and hence the need for this study.

This is an investigator-initiated multi-centre randomised controlled trial aiming to investigate how an approved and CE marked CADe device can support endoscopists on detection and diagnosis of colorectal polyps.

Who can participate?
Adults over 18 years who are undergoing a colonoscopy.

What does the study involve?
You will be allocated to have either a standard colonoscopy or a colonoscopy using the WISE VISION device.

Participants will not be able to choose which of these options they have. Instead, participants will be randomly assigned to one or the other. This is to make the trial fair and enable us to compare the two options accurately.

If participants are allocated to standard colonoscopy, participants will undergo the procedure in the usual way. If participants are allocated to colonoscopy with the use of the WISE VISION (CAD) device participants will still undergo a standard colonoscopy, as per usual, but there will also be an additional screen and computer programme used, during the procedure, to help us identify polyps. You do not have to undergo any additional or extra procedures to what would

usually be needed. In both groups, the participant's endoscopist will examine possible polyps and use their clinical judgement to decide on the appropriate treat the ment and management. The WISE VISION (CAD) device will not replace human assessment or alter any decision making during the participant's procedure.

What are the possible benefits and risks of participating?
This study will have no direct benefit to participants.
There are no additional risks of taking part in this study.

Where is the study run from?
Portsmouth Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?
November 2022 to December 2024

Who is funding the study?
NEC Corporation (Japan)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Type(s)
Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
313559

Central Portfolio Management System (CPMS)
54150

Study information

Scientific Title
Real time computer aided detection and characterisation of colorectal polyps; a prospective multi-centre randomised controlled superiority trial (ColoVision)

Acronym
ColoVision

Study objectives
The CAD device used in this study (WISE VISION®) can significantly improve endoscopists' adenoma detection rate (ADR) as well as their real time optical diagnosis to reach PIVI threshold of 90% NPV, compared to endoscopists not using the CAD device.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 29/11/2022, London - Bloomsbury Research Ethics Committee (HRA RES Centre Manchester, 3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ, United Kingdom; +44 2071048272; bloomsbury.rec@hra.nhs.uk), ref: 22/PR/1174

Primary study design
Interventional

Study design
Interventional randomized controlled trial

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Detection and diagnosis of colorectal polyps

Interventions
Participants will be randomised to either standard colonoscopy or standard colonoscopy with CAD support. The addition of the CAD system means an extra screen will be in the endoscopy

suite. There is no additional procedure or follow up for participants. Participants will undergo their colonoscopy and the number of polyps detected in each group will be recorded. Additional information regarding diagnosis (assessment of size, shape and type of polyp by both the endoscopist and the CADx system) will also be assessed. Polyps which are identified will be assessed and managed according to standard care.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
CAD system

Primary outcome(s)
Adenoma detection rate in both groups. PIVI-2: NPV of adenoma diagnosis in diminutive (<5mm) rectosigmoid polyps in both groups measured during procedure

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

Completion date
08/12/2024

Eligibility

Key inclusion criteria
1. Adults over 18 years who are undergoing a colonoscopy
2. Able to give informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Pregnant patients
2. Poor bowel preparation
3. Polyposis syndrome

4. Inflammatory bowel conditions
5. Incomplete colonoscopy

Date of first enrolment
08/02/2023

Date of final enrolment
08/06/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Worthing Hospital
Lyndhurst Road
Worthing
United Kingdom
BN11 2DH

Study participating centre
St Georges Hospital (wandle Annexe)
St. Georges Hospital
Blackshaw Road
Tooting
London
United Kingdom
SW17 0QT

Study participating centre
King's College Hospital
Denmark Hill
London
United Kingdom
SE5 9RS

Study participating centre
Queen Alexandras Hospital
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Sponsor information

Organisation
Portsmouth Hospitals NHS Trust

ROR
https://ror.org/009fk3b63

Funder(s)

Funder type
Industry

Funder Name
NEC Corporation

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Japan

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?
	version 1.1				

Participant information sheet	version 1.0	01/11/2022	08/06/2023	No	Yes
Protocol file		18/08/2022	08/06/2023	No	No