# ColoVision: Using computers to instantly find and describe colorectal polyps

Submission date 30/01/2023	<b>Recruitment status</b> No longer recruiting	Prospectively registered		
		[X] Protocol		
Registration date	Overall study status	[] Statistical analysis plan		
31/08/2023	Completed	[_] Results		
Last Edited 31/08/2023	<b>Condition category</b> Digestive System	Individual participant data		
		[_] 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? Katie.siggens@porthosp.nhs.uk

## **Contact information**

**Type(s)** Scientific

**Contact name** Miss Katie Siggens

#### **Contact details**

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**Type(s)** Principal Investigator

**Contact name** Prof Pradeep Bhandari

#### **Contact details**

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## Additional identifiers

**EudraCT/CTIS number** Nil known

**IRAS number** 313559

**ClinicalTrials.gov number** Nil known

**Secondary identifying numbers** CPMS 54150, IRAS 313559

## 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

**Study design** Interventional randomized controlled trial

**Primary study design** Interventional

**Secondary study design** Randomised controlled trial 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

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

Pharmaceutical study type(s) Not Applicable

**Phase** Not Applicable

Drug/device/biological/vaccine name(s)

CAD system

#### Primary outcome measure

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

#### Secondary outcome measures

There are no secondary outcome measures

## Overall study start date 29/11/2022

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

#### Age group

Adult

#### Lower age limit

18 Years

**Sex** Both

**Target number of participants** Planned Sample Size: 654; UK Sample Size: 400

#### Key exclusion criteria

Pregnant patients
Poor bowel preparation
Polyposis syndrome
Inflammatory bowel conditions
Incomplete colonoscopy

Date of first enrolment 08/02/2023

Date of final enrolment 08/06/2024

## Locations

**Countries of recruitment** England

United Kingdom

#### 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 Southwick Hill Road

Cosham Portsmouth United Kingdom PO6 3LY

### Sponsor information

#### **Organisation** Portsmouth Hospitals NHS Trust

#### Sponsor details

Queen Alexandra Hospital Southwick Hill Road Cosham Portsmouth England United Kingdom PO6 3LY +44 2392 286236 Joe.Shoebridge@porthosp.nhs.uk

#### Sponsor type

Hospital/treatment centre

#### Website

http://www.porthosp.nhs.uk/

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**

**Publication and dissemination plan** Planned publication in a high-impact peer-reviewed journal

Intention to publish date 31/12/2025

#### 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 1.1	01/11/2022	08/06/2023	No	Yes
Protocol file	version 1.0	18/08/2022	08/06/2023	No	No