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PARTICIPANT INFORMATION SHEET

COLOVISION

Real-time Computer-aided Detection and Characterisation, of Colorectal Polyps: A Prospective Multicentre Randomised Controlled Superiority Trial

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IRAS ID: 313559

Researchers:

Prof Pradeep Bhandari- Consultant Gastroenterologist, Portsmouth Hospitals University NHS Trust

Miss Katie Siggens- Endoscopy Research Fellow, Portsmouth Hospitals University NHS Trust

You are invited to take part in this trial organised by Portsmouth Hospitals University NHS Trust to evaluate whether a computer aided detection (CAD) system called WISE VISION® improves detection and diagnosis of polyps in the bowel during colonoscopy. Before you agree to take part in this trial, you need to understand what it will involve for you and why this research is being carried out. To help you decide whether to take part this information sheet has been produced. Please read it carefully, and if you have any questions then your local research team will be able to help answer them and provide any additional information you may require at any point.

Why have I been invited to take part?

You have been invited to take part as you are due to undergo a colonoscopy at your local hospital.

What is the purpose of the study?

Polyps are small growths in the lining of the bowel which over the course of many years have potential to turn into cancerous areas. Because we know there is this small risk, if we identify polyps during colonoscopy, we usually remove them. However, we know that small polyps can be missed during colonoscopy which has led to interest in improving polyp detection.

Before we introduce a new technology or treatment, we need to know that it will benefit patients. We know from studies that CAD can correctly identify polyps, but these studies have been largely based on videos or photos and larger trials in real-time are needed. This study is called a randomised trial. This means we will have two groups of patients who are randomly allocated to either a standard colonoscopy or a standard colonoscopy with the WISE VISION® CAD device. This allows us to compare and test whether this new technology improves what we currently do.

The main aim of this study is to test whether the CAD system (WISE VISION®) improves the detection and diagnosis of polyps in the bowel during colonoscopy.

What does the study mean for me?

If you agree to take part in the study, you will be allocated to have either a standard colonoscopy or a colonoscopy with the use of the WISE VISION® device.

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

If you are allocated to standard colonoscopy, you will undergo the procedure in the usual way. If you are allocated to colonoscopy with the use of the WISE VISION® (CAD) device you 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, your endoscopist

will examine possible polyps and use their clinical judgement to decide on the appropriate treatment and management. The WISE VISION® (CAD) device will not replace human assessment or alter any decision making during your procedure.

Do I have to take part in the study?

It is entirely voluntary whether you agree to take part in the trial or not. If you decide to take part, you will be asked to sign a consent form specifically for this trial. At any point in the trial, you are free to change your mind and stop taking part in the study. This will not in any way change or alter the care that you receive. If you decide to withdraw from the trial, we will collect no further data about you, but we will keep the data that has already been collected.

How will I be treated if I do not take part?

The colonoscopy procedure you undergo will be carried out in the standard way and your care will not be affected in anyway.

What are the benefits of taking part?

If you decide to take part, this study will have no direct benefit to you; however, your participation will help guide future practice to potentially improve patient care. You will not receive any financial payment for taking part.

What are the disadvantages or risks of taking part?

There are no additional risks of taking part in this study. You will still undergo the same colonoscopy procedure and have the same follow up. Moreover, the WISE VISION® (CAD) device is not designed to replace your endoscopist if you are allocated to this group. It is designed to support the finding of polyps and at no point will the device be able to overrule your endoscopist.

Will my taking part be kept confidential?

All information collected during the research trial will be kept confidential. You will be allocated an anonymous ID number and any data directly related to you will be removed. We will write to your General Practitioner (GP) to inform them you are

participating in this trial. The results of the study will be published in scientific journals but will contain no information which is identifiable to you.

How will we use information about you?

We will need to use information from you and your medical records for this research project.

This information will include your initials, NHS number, age & gender. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

If you choose to stop taking part in the study, we would like to continue collecting information about your health from your hospital. If you do not want this to happen, tell us and we will stop.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/ or https://www.porthosp.nhs.uk/research/
- our leaflet available from http://www.hra.nhs.uk/patientdataandresearch
- by asking a member of the main research team in Portsmouth by calling: 02392 286000 ext. 5852
- by sending an email to research.office@porthosp.nhs.uk, or
- by ringing 02392 286000 and asking to speak to Emile Armour, Information Governance Manager at Portsmouth Hospitals University NHS Trust.

Who has reviewed this study and is it safe?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. They are there to protect you. This study has been given a favourable opinion by London - Bloomsbury Research Ethics Committee, reference 22/PR/1174 as well as the Health Research Authority. This means they have read about the study, interviewed the lead researcher and have no concerns with this project.

It is a requirement that your records in this research, together with any relevant medical records, be made available for scrutiny by monitors from the Sponsor, Portsmouth Hospitals NHS Trust or a delegated third party of the Sponsor, and UK research governance authorities, whose role is to check that research is properly conducted and the interests of those taking part are adequately protected.

What if new information arises while the study is ongoing?

If we find out new information relevant to the trial, you will receive written communication from the Chief Investigator about this. You will be able to contact the research team to discuss any questions you may have related to this.

What will happen to the results of the study?

We aim to publish the results in scientific journals to help guide further practise. You will not be identifiable in any way in this report. If you would like to know the results of the trial once it is completed, you will be able to access this by letting our research team know.

Who is funding and setting up the trial?

The trial is being funded by NEC Corporation, Ltd. This is a company based in Japan who have produced the technology (WISE VISION®) being tested in the trial. The technology they have created has undergone rigorous testing and been approved for its use in Europe, a process called CE Marking. The sponsor for this study is Portsmouth Hospital University NHS Trust.

What if there is a problem?

Should you have any concerns or complaints you have during the study, a member of the research team will try to address them. You can contact them on [telephone no. and email of local research team].

If you remain unhappy or concerned, you can make a formal complaint to the hospital Patient Advice and Liaison Service (PALS) who can be contacted by phone on [local PALS number] or by email [local PALS email].

You will be receiving standard medical care during this trial. If you unfortunately experience a complication during your colonoscopy procedure, you will receive the required medical care, but there will be no special compensation available as these risks are part of the procedure rather than related to the trial.

If in the event you are harmed due to negligence during the course of the research trial, the normal NHS complaints system is available to you should you wish to pursue legal action against the sponsor Portsmouth Hospital University NHS Trust or the NHS site where you received your care.

What if I have any questions?

If you have any questions which have not been answered by this information sheet, please contact the gastroenterology research department for help with these using the details at the end of this information sheet.

What happens next?

Having read this information sheet, if you wish to take part, you will be approached to sign a consent form for the trial. Should you have any questions or concerns, these can be discussed and addressed prior to providing consent. You will then undergo your procedure according to which arm of the trial you are allocated to, and the anonymised data will be collected from this.

Thank you for taking the time to read this and considering whether you wish to participate.

Local Study Contact Details

Principal Investigator:

Research Nurses:

Tel:

Email:

Sponsor Study Contact Details:

Chief Investigator: Professor Pradeep Bhandari, Consultant Gastroenterologist

Phone: 02392 286000 ext. 6236

Research Office:

1st Floor Lancaster House,
Queen Alexandra Hospital,
Southwick Hill Road,
Cosham
Hampshire
PO63LY
Research.office@porthosp.nhs.uk
02392 286236