IRAS ref. 271876

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CONSCOP 2

CONSCOP 2 - Randomised controlled trial of contrast enhanced colonoscopy in the reduction of right-sided bowel cancer (with FORE AI)

Patient Information Sheet 3

We would like to invite you to take part in a research study. Please take time to read the following information carefully and decide whether you wish to take part. Talk to others about the study if you wish. Please ask us if anything is unclear or if you would like more information.

Summary

- We are inviting people in England, Wales and Scotland who are due to have a colonoscopy as part of the UK Bowel Cancer Screening Programme to take part in this research study called CONSCOP2.

- CONSCOP2 aims to find out whether or not it is better to use blue dye to help improve detection and removal of pre-cancerous growths (polyps) in your colon. If you consent to participate you will be randomly allocated to receive either a standard colonoscopy or a colonoscopy using blue dye.

- We would also like to offer you the option to participate in a linked study called FORE-AI which uses new technology that can help to automatically detect and instantly diagnose polyps. Participating in either or both of these studies will not affect your care in any way. If you are happy to participate in the FORE-AI study you will need to consent to **anonymised** video data from your colonoscopy being used for this purpose (where no one can identify whose bowel is seen from the inside on video). You can participate in CONSCOP2 but decline to participate in FORE-AI.

- All of this research has been approved by an NHS Research Ethics Committee, funded by the UK Department of Health (National Institute for Health Research), and sponsored by Cardiff University.

Why have I been invited?

We are inviting people in England, Wales and Scotland who are due to have a colonoscopy as part of the UK Bowel Cancer Screening Programme to take part in this research study.

What is the purpose of this study?

The UK Bowel Cancer Screening Programme has reduced the risk of death from bowel cancer by 15%. We believe this is because any pre-cancerous growths (polyps) seen during colonoscopy are removed before they get the chance to grow and cause problems later. There are a small number of people who develop cancer even though they had a colonoscopy as part of the screening programme. There is some evidence to suggest that these cancers could be caused by a certain type of flat polyp called a serrated polyp which can be difficult to find. Small studies have suggested that these polyps and may grow into cancer faster than the usual polyps.

This study investigates if spraying a blue dye in the upper large bowel helps the doctor to *detect* more flat polyps during the colonoscopy. By using this dye, your colonoscopy may take approximately 6 minutes longer than usual. We hope to find out through this study if this method works in practice and improves the detection and removal of more of flat polyps within the screening programme and consequently find and remove the flat polyps that may otherwise be hard to detect. Overall, we plan to recruit 2652 participants to take part in this study.

At the moment we do not know if spraying the dye in the upper large bowel is the best way to improve detection so we need to randomly assign people who are due to have a screening colonoscopy into two groups, one to have a standard colonoscopy and the other to have a colonoscopy using the dye spray. We will then be able to compare what happens between the two groups.

We hope you will agree to take part in this research study, but we understand if you do not want to. If you are interested, then the rest of this leaflet gives you more information.

Why do we think the use of blue dye (Indigo Carmine) will help?

The blue dye is a safe washable food colouring agent and is already used occasionally when looking for small polyps. We think that spraying the lining of the bowel with the blue dye will make it easier to find and remove small polyps. Please see the picture below which shows a flat polyp which is easier to see once spayed with dye. Extremely rarely there may be individuals with an allergy to food colouring and they will be excluded from taking part in the study.

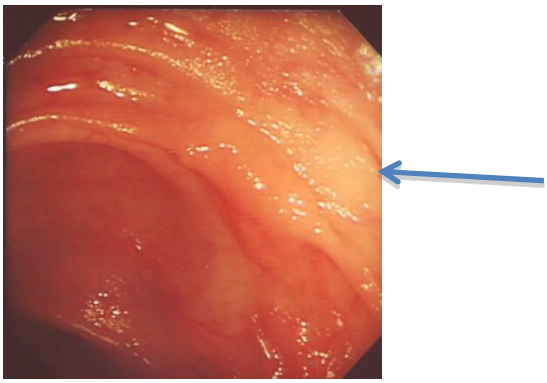
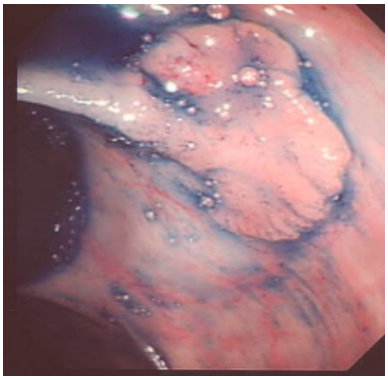


Figure 1a

You might be able to see a subtle abnormal area (arrow pointing to it), which is a flat polyp within the bowel and could easily be missed during colonoscopy



The **same polyp** has now been sprayed with blue dye. It is easier to see the full extent of the polyp.

Figure 1b

Do I have to take part?

No. It is up to you whether or not you want to take part. Deciding not to take part will not affect the standard of care you receive now or in the future.

What will happen if I do decide to take part?

When you attend for your colonoscopy you will be asked to give a signed copy of the informed consent form (a copy of which is at the end of this document) to say you have agreed to participate in the study. You will be given a copy of this form to keep, along with this information sheet.

If you decide to take part, then you will be randomly allocated a 50:50 chance by a computer to either have a standard colonoscopy without the dye or a colonoscopy with the dye.

The randomisation process assigns research participants by chance, rather than by choice, to either the treatment group or the control group of most clinical trials. Each study participant has a fair and equal chance of receiving either the new method of colonoscopy being studied (by being placed in the "treatment" group), or of receiving the existing method of colonoscopy (by being placed in the "control" group). The goal of randomisation is to produce comparable groups in terms of general participant characteristics, such as age or gender, and other key factors that affect the probable course a disease would take. In this way, the two groups are as similar as possible at the start of the study.

During the colonoscopy, you will be cared for in the normal way. Any polyps found in your colon will be removed and sent to your local laboratory for examination. The samples will then be sent for quality assurance checking by a group of NHS expert pathologists. This will involve sending the samples to Cardiff & Vale University NHS Health Board where they will be scanned, **anonymised**, and uploaded to a computer at Queens University Belfast.

The research team will then monitor your health for 30 days after the colonoscopy using routinely collected data.

We would also like to track your health status in the longer term through routinely collected national health data within the National Health Service (NHS) to see what effect this new colonoscopy method has on your future health. This information will use your NHS screening identifier, name and date of birth to enable the Centre for Trials Research (CTR) (a Cancer Research UK funded research unit at Cardiff University) to find out what happens to you in routinely collected national health datasets obtained from country specific registries.

What will happen if I don't want to carry on with the study?

You can decide not to participate in the study at any time, without giving a reason. This will not affect the standard of care that you receive now or in the future. In the unlikely event of you losing capacity to consent during the course of this trial, you will be withdrawn. However, any identifiable data or tissue already collected with consent would be retained and used in the study

What are the possible disadvantages and risks of taking part?

If you are randomised to the dye spray group then there are potential disadvantages, the colonoscopy procedure may take longer, especially if we find more polyps (on average 6 minutes more than the usual procedure). These extra polyps may never turn into cancer. Additionally, there may be an increased risk of complications (e.g. bleeding if polyps found are removed) although we believe this to be very unlikely.

If you are allocated to the standard colonoscopy then your experience should be exactly the same as it would have been if you were not taking part in the study i.e. as in the routine screening programme where polyps may be found and removed again as is part of usual care.

What are the possible benefits of taking part?

By participating in bowel screening you will already have taken steps to detect polyps and consequently reduce your risk for future bowel cancer. If you are randomised to the dye spray group, then we may detect and remove more polyps that could have turned into cancer, which further minimises the risk of future bowel 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.

Summary of the impact on you taking part or not in the study

Impact on you	Routine colonoscopy	Taking part in study and randomised to routine colonoscopy	Taking part in study and randomised to colonoscopy using blue dye
Bowel screening still goes ahead	Yes	Yes	Yes
Polyps when found usually removed	Yes	Yes	Yes
Blue dye spray used throughout the bowel	No	No	Yes
Time taken	30-60 minutes	30-60 minutes	6 minutes longer on average
Risks to you from colonoscopy and removal of polyps	Risk of perforation and bleeding. Same as standard as explained by the SSP Nurse to you	Risk of perforation and bleeding. Same as routine colonoscopy	More polyps may potentially be removed. Theoretically there may be a very small increased risk of complications if

			there are some additional polyps removed
Risks from blue dye to you	Not applicable None – no dye used	Not applicable None – no dye used	Very small chance of allergic reaction
Benefits to you	If cancer is present then it is often detected early. Other precancerous polyps found and can be treated/removed	Same as routine colonoscopy	More polyps may potentially be detected and removed than in routine colonoscopy. These polyps may have developed into cancer

What if there is a problem?

If you are unhappy with any aspect of the study, please speak with the Research Nurse in your hospital or contact the CONSCOP2 Trial Manager (e-mail: CONSCOP2@cardiff.ac.uk, who will do their best to help resolve the problem. Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. In the event that you are harmed during the research, and this is due to someone's negligence, then you may have grounds for legal action against the Sponsor (Cardiff University) and/or the NHS trust. However, you may have to pay your legal costs. If you remain unhappy and wish to complain formally, you can do this through the NHS complaints mechanism (or your private institute's complaints mechanism). Details can be obtained from your hospital.

How will we use information about you?

Cardiff University will need to use information from you and your medical records for this research project. This information will include your:

- Name and initials;
- NHS identifier;
- Date of birth;
- Details about your health and any further treatments or procedures you may undergo which are relevant to the study, both now and in the future.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. Individuals from CTR and regulatory organisations may use this information to check the accuracy of the research study.

What are your choices about how your information is used?

- You can withdraw from any part of the study at any time, without giving a reason, but we will keep information about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible.
- If you agree to take part in this study, you will have the option to take part in future research using your data, colonoscopy images and samples saved from this study. At this stage we do not know what the research will involve but some of it could include further research looking at how and why certain polyps form or a sub-study involving genetic research.

Will my taking part in this study be kept confidential?

All information that is collected about you during the course of the research will be kept strictly confidential.

Your Special Screening Practitioner or Research Nurse will assign a study number specifically to you and use this number to supply research data to the CTR, who are co-ordinating the study, and restrict reference to your personal details. Therefore, unauthorised personnel will not be able to see your name or other personal details and your data will have a code number instead. This information will be securely stored at the CTR office, on paper and electronically.

We will be using medical data about you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. This data will be kept securely at Cardiff University and you will not be identifiable in any reports or publications. Cardiff University will keep identifiable information about you for 15 years after the study has finished. If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study

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

You can find out more about how we use your information:

- by asking one of the research team by contacting the CONSCOP2 Trial Manager (e-mail: CONSCOP2@cardiff.ac.uk
- by viewing the Cardiff University Data Protection Policy: https://www.cardiff.ac.uk/public-information/policies-and-procedures/data-protection
- by contacting the Cardiff University Data Protection Officer: inforequest@cardiff.ac.uk/ Assurance Services, Cardiff University, Friary House, Greyfriars Road, Cardiff CF10 3AE.
- GDPR Privacy Notice: https://www.cardiff.ac.uk/centre-for-trials-research/research/studies-and-trials/view/CONSCOP2

What will happen to any samples I give?

Any samples of polyps found and removed from your bowel will be sent for their usual examination in the local laboratory. They will then be sent to Cardiff & Vale NHS Trust to be scanned for the purposes of the expert review described above before being returned to the local laboratory. We would also like your permission to request them from your local laboratory at some point in the future for academic (not for profit) research. This is **optional** (you can still take part in the trial even if you do not give permission for this) and we would remove any personal identifiable information from these samples before storing them. At this stage we do not know what the research will involve but some of it could include genetic research e.g. to assess the genetic make-up of the polyp. Your tissue will not be sold and will not be used in animal research or the commercial sector. Further ethical approval will be sought from the Ethics committee for any future research on these samples. All tissues will be supplied anonymously to researchers; only the CONSCOP2 research group will be able to identify which tissues you donated. The recipients of the tissue will not be supplied with your name or any other identifiable information and will not be able to identify you from the tissue. We will not use individual results, but will draw conclusions based on data from all participants who agree to take part. You will not be told of any specific results about your samples.

You may withdraw your consent for the storage and future use of your samples at any time. If you do withdraw your consent, your tissue will not be used in any subsequent studies and will be destroyed according to locally approved practices. Any tissue already distributed for research prior to the withdrawal of consent will continue to be used in that study and any tissue remaining at the end of the study will be destroyed.

The optional FORE-AI substudy

If you take part in the CONSCOP2 study we would also like to invite you to take part in another study called FORE-AI. FORE-AI has also been funded by the NIHR (and sponsored by Cardiff University) and is part of a UK Department of Health initiative aimed at improving and speeding up colorectal cancer screening by using computer aided detection (artificial intelligence): https://www.nihr.ac.uk/news/artificial-intelligence-research-to-speed-up-cancer-and-heart-care-as-part-of-nhs-ai-lab/25623

Participation is **optional** and you can take part in CONSCOP2 but choose to not to take part in FORE-AI.

During a routine colonoscopy, a camera on a scope sends video data to a screen for the Doctor to use to search for polyps in your colon. We are asking for your permission to be able to use a recording of this video to help develop new technology. This will not affect your colonoscopy procedure in any way. We hope that in the future this technology will help support Doctors to detect polyps more reliably and to diagnose them instantly. Currently any polyps removed by your Doctor are sent to another Doctor, a pathologist, to diagnose them which takes about 3 weeks. This slows down patient care and is expensive.

If you do take part then we will ensure that no one can tell whose bowel the video is from as it will only record the inside of the bowel and the video data will have any personal identifiable information removed from it before it is then sent to a UK company called Odin Vision. This will help Odin Vision develop the software. Cardiff University will also give Odin Vision **anonymised** data on the polyps found in your colon that is collected as part of the CONSCOP2 study . You will not be identifiable from any of the data that is given to Odin Vision.

What if relevant new information becomes available?

Sometimes we get new information about the condition being studied. If this happens, we will inform your doctor, who will tell you and discuss with you whether you should continue with the study. If the study is stopped for any other reason, we will tell you and your care by your doctor will continue as normal.

What will happen to the results of the research study?

At the end of the research, we will keep some of the data so we can check the results and a report will be completed and submitted to the National Institute for Health Research (NIHR) who are funding the study. Results will also be published in scientific journals and presented at national and international scientific conferences. You will not be identified in any report, publication or presentation; all results will be completely anonymous. If you would like a report of the research findings, these will be publicly available on the NIHR website following completion of the study. Please note that results will not be publicly available for several years after the study has ended.

Who is organising and funding the research?

This study is being sponsored by Cardiff University (where the Chief Investigator of the study works) and is being managed by the CTR at Cardiff University. It is funded by the NIHR at the Department of Health in the UK.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a research ethics committee to protect your safety, rights, well-being and dignity. This study has been reviewed by an NHS Research Ethics Committee (Wales REC 6). It has also received competitive independent peer review by a committee of experts for the NIHR as part of their funding process.

Contact for Further Information:

Please contact your Specialist Screening Nurse or Research Nurse ***<INSERT CONTACT NUMBER(s)>*** *for any queries relating to this study.*

THANK YOU FOR CONSIDERING TAKING PART IN THE STUDY.

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CONSCOP 2 - Randomised controlled trial of contrast enhanced colonoscopy in the reduction of right sided bowel cancer (with FORE AI)

Participant Consent Form

If you would like to participate in this study, then please read and **initial boxes** 1-7 (and optionally 8, 9 and 10) below:

1. I confirm that I have read and understood the patient information sheet (v1.0, Nov 2020) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my care being affected. ☐

3. I give consent for my medical records to be examined by the Cardiff University research team on the understanding that all information will remain confidential. I understand that data collected during the study may be looked at by responsible individuals from the Cardiff University research team, the NHS or from the regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records. ☐

4. I agree to allow the research team to follow up my health status using routinely collected health data within cancer registries and national screening programmes. I give permission for my NHS identifier, date of birth, and name to be sent to Cardiff University to allow this to happen. ☐

5. I give permission for any identifiable data collected to be retained and used for study purposes should I lose capacity. I understand that this data will remain confidential. ☐

6. I give consent for any polyps found to be **anonymised**, scanned, and uploaded to Queens University Belfast for review by expert pathologists within the UK NHS for quality assurance purposes. ☐
7. I agree to take part in the above study. ☐

Optional points 8, 9 and 10.

Please take time to read the following **optional** points below. Participation in the following is optional so you can take part in the main study but refuse to give us permission for any of the points below.

If you would like to take part in any of these optional parts of the study, then please initial any (or all) of the boxes 8-10 that apply.

8. **OPTIONAL**: I give consent for any polyps found to be requested by Cardiff University for future research. I understand that these samples will have been **anonymised** before being sent to Cardiff University. I consent for any of my tissue retained to be used in future research within the UK and abroad which may include genetic research and linking to **anonymised** data about me collected in CONSCOP2. I understand that my tissue will not be sold and will not be used in animal research or the commercial sector. ☐

9. **OPTIONAL**: I give consent for **anonymised** data collected about me in this study to be used in future academic research aimed at improving health outcomes for NHS patients. ☐

10. **OPTIONAL**: I give consent to an **anonymised** video of my colonoscopy to be used in the FORE-AI research project described above. ☐

TO BE COMPLETED BY THE PARTICIPANT USING BLOCK CAPITALS PLEASE:

Name of Participant (please print):	Date:	Signature:
_____	_____	_____

To be completed by the member of the UK Bowel Screening team who takes consent:

Name of Person taking consent (please print):	Date:	Signature:
_____	_____	_____

Patient's Trial Number**:** (from randomisation) | | | | | | | BSW/NHS/CHI ID:_____

Please place a copy in your Site File, a copy in the Patient's Notes and give a copy to the patient.