ISRCTN98539180 https://doi.org/10.1186/ISRCTN98539180

Randomised controlled trial of contrast-enhanced colonoscopy in the reduction of right-sided bowel cancer

Submission date
21/01/2020

Recruitment status
No longer recruiting

Registration date
19/02/2020

Overall study status
Ongoing

Last Edited
23/02/2024

Condition category
Cancer

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The UK Bowel Cancer Screening Programme has reduced the risk of death from bowel cancer by 15%. People testing positive on a bowel cancer screening stool test are offered colonoscopy (bowel camera examination) through the UK Bowel Cancer Screening Programme. About half of those have cancers or polyps (small abnormal growths that might lead to cancer in the future) found on colonoscopy. 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 detect during standard colonoscopy. Small studies have suggested that these polyps and may grow into cancer faster than the usual polyps and up to 1 in 5 bowel cancers may actually have developed from these subtle serrated polyps. Moreover, deaths from cancer of the upper bowel are not reducing. This study will investigate if spraying a blue dye in the upper large bowel helps the doctor to detect more flat polyps during the colonoscopy. At the moment it is not known if spraying the dye in the upper large bowel is the best way to improve detection so participants who are due to have a screening colonoscopy will be randomly assigned into two groups; one to have a standard colonoscopy and the other to have a colonoscopy using the dye spray. This will allow a comparison of what happens between the two groups. The aim is to find out through this study if this method works in practice and improves the detection and removal of more serrated polyps within the screening programme.

Who can participate?
All participants in the UK bowel screening programmes (Wales, England, Scotland) who test positive on the FIT test (bowel cancer screening stool test) and are eligible for an index screening colonoscopy. Participants will only be ineligible for the study if they have received previous resectional colorectal surgery (as this would influence both study methods and outcomes depending on the length of residual colon in the individual), and/or have a 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).

What does the study involve?
Participants are randomly allocated into two groups; one to have a standard colonoscopy and

the other to have a colonoscopy using the dye spray. They are followed up through routinely collected data systems.

A subset of participants may take part in the FORE AI substudy (https://www.isrctn.com/ISRCTN15467766).

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 that the Chief Investigator, Dr Sunil Dolwani, is based at.

When is the study starting and how long is it expected to run for?
June 2019 to December 2025

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

Who is the main contact?
Georgina Gardner
CONSCOP2@cardiff.ac.uk

Contact information

Type(s)
Public

Contact name
Mrs Georgina Gardner

Contact details

Centre for Trials Research
College of Biomedical & Life Sciences
Cardiff University
6th Floor, Neuadd Meirionnydd
Heath Park
Cardiff
United Kingdom
CF14 4YS
+44 (0)2920 687 950
CONSCOP2@cardiff.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
271876

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
SPON 1781-19, CPMS 44738, IRAS 271876

Study information

Scientific Title
Randomised controlled trial of contrast-enhanced colonoscopy in the reduction of right-sided bowel cancer (the CONSCOP 2 study)

Acronym
CONSCOP 2

Study objectives
Primary hypothesis:
1. Proximal advanced serrated lesion (SL) detection rates will be greater when spraying blue indigo carmine dye throughout the upper large bowel during colonoscopy (chromocolonoscopy) when compared to a standard colonoscopy without dye

Secondary hypotheses:
1. Other lesion detection rates (e.g. advanced neoplasia, serrated lesions, advanced adenomas) will be greater using chromocolonoscopy when compared to standard colonoscopy
2. Faecal immunochemical test (FIT) thresholds will impact on the SL detection rates in each arm of the study

Secondary objectives:
1. Evaluate the longer-term economic impact of chromocolonoscopy within the screening setting
2. Model and compare the post-colonoscopy interval advanced polyp and cancer detection and

death rates for the two arms
3. Assess the association between demographic and lifestyle factors and SLs at index colonoscopy
4. Assess the association between demographic and lifestyle factors and SLs at surveillance colonoscopies in order to inform the stratification and optimisation of surveillance frequency

A subset of participants may take part in the FORE AI substudy (https://www.isrctn.com/ISRCTN15467766).

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 26/02/2020, Wales REC 6 (Health and Care Research Wales Support and Delivery Centre, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, United Kingdom; +44 (0) 1874 615949; Wales.REC6@wales.nhs.uk), ref: 20/WA/0019

Study design
Multicentre open-label individually randomised (1:1) controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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

Interventions
A randomised open controlled trial (RCT) of chromocolonoscopy (spraying blue indigo carmine dye throughout the upper large bowel during colonoscopy) vs a standard colonoscopy without dye in index bowel cancer screening to reduce bowel cancer mortality. CONSCOP2 will recruit 2652 participants from ~20 centres in England, Wales and Scotland attending index colonoscopies within the bowel screening programme and will follow them up through routinely collected data systems. The data obtained in this study will establish whether or not chromocolonoscopy should be used instead of standard white light for index colonoscopies within the UK bowel cancer screening programmes.

A subset of participants may take part in the FORE AI substudy (https://www.isrctn.com/ISRCTN15467766).

Intervention Type
Procedure/Surgery

Primary outcome measure
Detection of any proximal advanced serrated lesions as defined by pathological assessment at index colonoscopy (colonoscopy intervention)

Secondary outcome measures
1. Pathological types and counts of all polyps detected at index procedure (colonoscopy intervention)
2. Pathological types and counts of all polyps detected at surveillance procedure (up to 1 year after repeat procedures). Types of all polyps detected at surveillance procedures will be obtained from local histopathology reports and routinely collected screening datasets
3. Cancers and deaths obtained from routinely collected health datasets (follow up for 3 years)

Overall study start date
18/06/2019

Completion date
01/12/2025

Eligibility

Key inclusion criteria
All FIT-positive people in the participating centres, eligible for index screening colonoscopy using high definition scopes

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
2652

Total final enrolment
2750

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. 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)

Date of first enrolment
23/07/2021

Date of final enrolment
09/02/2024

Locations

Countries of recruitment
England

Scotland

United Kingdom

Wales

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

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

Study participating centre
Cardiff & Vale University LHB
Corporate Headquarters
Heath Park
Cardiff
United Kingdom
CF14 4XW

Study participating centre
Cwm Taf University LHB
Cwm Taf University LHB
Dewi Sant Hospital
Albert Road
Pontypridd
United Kingdom
CF37 1LB

Study participating centre
North Tees and Hartlepool NHS Foundation Trust
University Hospital Of Hartlepool
Holdforth Road
Hartlepool
United Kingdom
TS24 9AH

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
Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Study participating centre
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
Kettering General Hospital
Rothwell Road
Kettering
United Kingdom
NN16 8UZ

Study participating centre
Russells Hall Hospital
Pensnett Road
Dudley
United Kingdom
DY1 2HQ

Study participating centre
Bradford Royal Infirmary
Duckworth Lane
Bradford
United Kingdom
BD9 6RJ

Study participating centre
Cheltenham General Hospital
Sandford Road
Cheltenham
United Kingdom
GL53 7AN

Study participating centre
Nottingham University Hospital
Trust Hq, Qmc Campus
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Sherwood Forest Hospitals NHS Foundation Trust
Kings Mill Hospital
Mansfield Road

Sutton-in-ashfield
United Kingdom
NG17 4JL

Study participating centre
Royal Derby Hospital
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

Study participating centre
Leeds Teaching Hospitals NHS Trust
St. James's University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
University Hospital of North Durham
University Hospital of Durham
Dryburn Hospital
North Road
Durham
United Kingdom
DH1 5TW

Sponsor information

Organisation
Cardiff University

Sponsor details
Research Governance Coordinator Research and Innovation Services Cardiff University
7th Floor, McKenzie House,
30-36 Newport Rd
Cardiff
Wales
United Kingdom
CF24 0DE

+44 (0)29208 79130
ShawC3@cardiff.ac.uk

Sponsor type
University/education

Website
http://www.cardiff.ac.uk/

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Data from all sites will be analysed together and published as soon as possible. Individual participating PIs may not publish data concerning their participants that are directly relevant to questions posed by the trial until the TMG has published its report. The TMG will form the basis of the writing committee and advise on the nature of publications, subject to the Sponsor's requirements. Publication will be according to the publication policy of the CTR and the CONSCOP2 publication plan.
Principles regarding authorship and writing:
1. All proposals for publications using CONSCOP2 data must be approved by the TMG
2. A lead author and wider writing team will be established for each identified paper

3. All potential contributors will have the opportunity to opt into a writing team
4. It is the responsibility of the Chief Investigator (CI) and Study Lead to ensure balance and inclusivity in writing teams across the range of likely study publications, to ensure everyone is appropriately acknowledged and has the opportunity to be involved as an author
5. It is the responsibility of the CI to decide authorship order, usually in discussion with the lead author and Study Lead
6. All named authors must meet authorship criteria (e.g. see http://www.bmj.com/about-bmj/resources-authors/article-submission/authorship-contributorshipauthorship))
7. Submission of abstracts for conference presentation should be agreed in advance with the TMG. Authors should allow sufficient time for their request to be reviewed. This may be completed via email. However, if there is insufficient time for the TMG to review such a request, the CI can make a decision on behalf of the TMG. The body of the presentation (including posters) should be reviewed by the TMG prior to presentation. This may be completed via email

Intention to publish date
01/09/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available on request upon consideration by the TSC and TMG. When enrolling for the trial, participants will provide their permission for the Sponsor (Cardiff University) to access their medical records through routinely collected cancer registries and national screening programmes. This will be used to follow up the health status of all participants. Participants will not be identified in any report, publication or presentation; all results will be completely anonymous.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 4	17/11/2020	17/01/2023	No	No
HRA research summary			28/06/2023	No	No