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Water assisted flexible sigmoidoscopy in NHS Bowel Scope Screening Programme

Submission date
04/04/2018

Recruitment status
No longer recruiting

Registration date
12/04/2018

Overall study status
Completed

Last Edited
29/06/2021

Condition category
Digestive System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Bowel cancer is the second most common cause of cancer death in the UK. Around 1 in 14 men and 1 in 19 women will develop bowel cancer. To reduce this risk, the NHS Bowel Screening Programme has started inviting all 55 year olds for a sigmoidoscopy. This involves examining the lower bowel with a thin flexible tube with a camera on it, via the back passage. Research has shown that this test reduces bowel cancer death by 41%. During the test, the bowel is inflated with carbon dioxide, to allow passage of the camera. The problem is that bowel distention can cause pain. National surveys show that over 1 in 3 patients report moderate or severe pain. The aim of this study is to assess whether using water to minimise bowel distension, instead of gas, will make the procedure more comfortable. Early studies suggest this may be effective, but this needs to be confirmed in UK practice. It is hoped that by reducing pain, people will have a better experience, which may increase public uptake of screening. Currently only 43.7% of people participate –more cancers can be prevented if participation increases.

Who can participate?
Healthy volunteers referred for screening flexible sigmoidoscopy via the NHS Bowel Scope Screening Programme

What does the study involve?
Participants are randomly allocated to either have the current standard sigmoidoscopy using carbon dioxide, or to have sigmoidoscopy using water. Participants are then asked how comfortable they found the test. The study also measures which technique finds more polyps (small growths that may have cancerous potential).

What are the possible benefits and risks of participating?
The endoscopists performing the procedure may be able to deliver a more comfortable procedure for patients and may also be able to find more polyps. The study may not benefit the participants now, but the results may help others who have sigmoidoscopy in the future. There have been no safety issues reported with water-assisted sigmoidoscopy in any study so far. Discomfort is a possibility in either type of sigmoidoscopy procedure (normal CO2

sigmoidoscopy and water-assisted sigmoidoscopy). As part of the study side effects (such as discomfort and incontinence during or after the procedure) as well as overall experience during the flexible sigmoidoscopy are measured.

Where is the study run from?
1. North Tees and Hartlepool NHS Foundation Trust (UK)
2. St Mark's Hospital, London (UK)
3. South Tyneside NHS Foundation Trust (UK)
4. Queen Elizabeth Hospital Gateshead (UK)
5. County Durham and Darlington NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
June 2017 to November 2019

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

Who is the main contact?
Mrs Jill Deane
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
35866

Study information

Scientific Title
The WASH study: water assisted sigmoidoscopy in NHS Bowel Scope Screening Programme: a randomised multicentre study

Acronym
WASH

Study objectives
1. Water-assisted sigmoidoscopy (WAS) will lead to decreased procedural pain, when compared with standard CO2-assisted (CO2) insertion, resulting in better patient experience during screening
2. WAS improves other key screening performance indicators such as the adenoma (cancer precursor) detection rate

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North East, 10/11/2017, ref: 17/NE/0309

Study design
Randomised; Interventional; Design type: Treatment, Other

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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
Other examination or investigation

Interventions
Patients will be randomised using a secure, web-based platform that can be accessed 24 hours a day, which was developed and is maintained by NWORTH. The randomisation uses dynamic allocation to ensure a consistent balance to the allocation ratio of 1:1 and within any stratification variable.

Treatment: water-assisted flexible sigmoidoscopy (FSIG) utilising the WAS technique
Control: standard CO2 assisted flexible sigmoidoscopy

The trialists will then ask patients how comfortable they found the test and measure which technique finds more adenomas. Follow-up is for 14 days following procedure (sigmoidoscopy).

Intervention Type
Procedure/Surgery

Primary outcome measure
Pain is measured using a standard Likert scale (4-point) ("None/ Mild / Moderate / Severe") post-procedure/pre-discharge and 24 hours afterwards via patient questionnaire

Secondary outcome measures
The key secondary outcome will be the adenoma detection rate (ADR), the key performance indicator for the accuracy of sigmoidoscopy in detecting pre-malignant polyps (adenomas). This is measured at 14 days following review of all histology reports of patient who have polyps removed

Other secondary measures include:
1. Procedural pain as rated by patients on a Visual Analogue Scale (VAS) immediately after procedure [post-procedure, pre-discharge]
2. Other aspects of patients' experience, by a post-discharge questionnaire assessing embarrassment, willingness to repeat the procedure, expected versus experienced pain, overall satisfaction and symptoms post-procedure.
3. The sigmoidoscopy insertion times (SITs)
4. The sigmoidoscopy withdrawal times (SWTs) in negative procedures (i.e. without polyps)
5. The maximum extent of insertion (segment, i.e. rectum, distal sigmoid, proximal sigmoid, distal descending, proximal descending, splenic flexure, distal transverse; as judged by the endoscopist) – this will be the primary means to estimate extent of insertion
6. The final length of scope inserted just prior to withdrawal (scope length in cm) – this will be used as a surrogate for how straight/looped the scope is (stratifying by segment extent)
7. The mean number of adenomas per procedure (MAP)
8. The percentage of procedures where Entonox was used on demand (i.e. as an adjunct in case of procedural pain per patient's wish). This will not be applicable in procedures where participants prefer to start their procedure with Entonox use
9. The quality of mucosal views on withdrawal using the validated Boston Bowel Preparation Scale
10. The percentage of procedures where a second enema was needed (due to poor mucosal views)
11. The percentage of procedures where hand pressure was required (ancillary manoeuvre to aid insertion)
12. The percentage of procedures where patient position shifts were required (ancillary manoeuvre to aid insertion)
13. The conversion rate from WAS to CO2, or CO2 to WAS technique
14. The volume of water and CO2 used in WAS and CO2 arms
15. The number and type of endoscope loops identified with magnetic scope guide (where scope guide used)
16. The endoscopist learning curve of WAS technique during the training period (prior to commencing the trial) by capturing endoscopists' reported confidence in performing the procedure, their attitude towards the technique (negative, neutral, positive) before and after

completion of training period, as well as procedure times and extent of insertion as the study progresses

These outcomes will be analysed on an intention to treat basis. Following this; as per protocol analysis will be considered as appropriate to assess the sensitivity of these results. Exploratory subgroups analyses will be considered for relevant cohorts with previous hysterectomy, irritable bowel syndrome and diverticulosis, as well as for depth of scope insertion (segment and length of scope), scope diameter (adult vs. paediatric) and model (e.g. Olympus 240/260/290) and individual endoscopists all considered.

Overall study start date
01/06/2017

Completion date
30/11/2019

Eligibility

Key inclusion criteria
1. Referral for screening flexible sigmoidoscopy via the NHS Bowel Scope Screening Programme
2. Ability to give informed consent

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 1100; UK Sample Size: 1100

Total final enrolment
1125

Key exclusion criteria
1. Absolute contraindications to sigmoidoscopy
2. Patients lacking capacity to give informed consent
3. Previous left colonic/rectal resection
4. Ongoing antithrombotic treatment (apart from aspirin, which is permitted)

Date of first enrolment
01/12/2017

Date of final enrolment
06/06/2019

Locations

Countries of recruitment
England

United Kingdom

Yemen

Study participating centre
North Tees and Hartlepool NHS Foundation Trust
United Kingdom
TS19 8PE

Study participating centre
St Mark's Hospital
London
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Study participating centre
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Sponsor information

Organisation

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04zzrht05

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: PB-PG-1215-20035

Results and Publications

Publication and dissemination plan
Results of the study will be published in an international journal and will be communicated to the Bowel Cancer Screening Programme and to patients and doctors internationally.

Intention to publish date
01/12/2020

Individual participant data (IPD) sharing plan
Once the trial is complete and all data collection, data cleaning, data analysis and reports are complete the Chief Investigator will be issued with a trial data pack by NOWRTH (all data will be anonymised). Chief Investigator is Professor Matt Rutter (Matt.Rutter@nth.nhs.uk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Protocol article	protocol	01/11/2019	15/11/2019	Yes	No
Results article		07/09/2020	29/06/2021	Yes	No
HRA research summary			28/06/2023	No	No