

Water assisted flexible sigmoidoscopy in NHS Bowel Scope Screening Programme

Submission date 04/04/2018	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 12/04/2018	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 29/06/2021	Condition category Digestive System	☐ 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

Contact name

Mrs Jill Deane

Contact details

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised; Interventional; Design type: Treatment, Other

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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**

United Kingdom

England

Yemen

Study participating centre

North Tees and Hartlepool NHS Foundation Trust

United Kingdom

TS19 8PE

Study participating centre

St Mark's Hospital

London

United Kingdom
HA1 3UJ

Study participating centre
South Tyneside NHS Foundation Trust
United Kingdom
NE34 0PL

Study participating centre
Queen Elizabeth Hospital
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NE9 6SX

Study participating centre
County Durham and Darlington NHS Foundation Trust
Yemen
DL3 6HX

Sponsor information

Organisation
North Tees & Hartlepool NHS Foundation Trust

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

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