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Can additional bowel preparation improve the detection of disease in the bowel using ultrasound?

Submission date
12/06/2024

Recruitment status
Recruiting

Registration date
19/06/2024

Overall study status
Ongoing

Last Edited
01/08/2025

Condition category
Digestive System

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

Plain English summary of protocol

Background and study aims
All patients who are scheduled to have a computed tomography faecal tagging colonography (CTC) scan follow a special bowel preparation routine 2 days before the scan. This is to ensure the bowel is as empty as possible. This involves following a low residue diet (a diet which contains little or no fibre/roughage) and drinking a liquid medication called Gastrografin. Currently, patients who are having an ultrasound scan of their bowel do not follow this preparation. The purpose of this research study is to see if giving bowel preparation to patients who are having a bowel ultrasound scan will improve the accuracy of these scans. In turn, this will demonstrate if ultrasound of the bowel has the potential to be used instead of CT scans in some patients when they are given bowel preparation.

Who can participate?
Adult patients aged 18 years old and over who are having a CTC scan under their routine care

What does the study involve?
Everyone who agrees to be part of the study will be asked to sign a consent form and will be invited for one ultrasound scan 30 minutes before their CTC scan appointment. The ultrasound scan will be performed by a specialist Radiology Doctor or specialist Sonographer and will take up to 30 minutes, where they will then continue for your CT scan afterwards.

What are the possible benefits and risks of participating?
There are no direct benefits to taking part in this study. The main benefits are contributing to the improvement of ultrasound practice in the future. Currently, patients having an ultrasound of their bowel are not given any preparation to take. If the accuracy of ultrasound is shown to be higher using bowel preparation in this study, the future practice could be changed to improve patient outcomes. Ultrasound is very safe with no side effects, there are no known risks to taking part.

Where is the study run from?
Queen Alexandra Hospital

When is the study starting and how long is it expected to run for?
June 2024 to May 2027

Who is funding the study?
1. Society of Radiographers
2. College of Radiographers
3. National Institute for Health and Care Research (NIHR)

Who is the main contact?
Dr Ruth Reeve, ruth.reeve@porthosp.nhs.uk

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
334186

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 62618, IRAS 334186

Study information

Scientific Title

ENPIC (ENhanced Preparation In Colonic) Ultrasound: a study protocol for a single centre, non-randomised, single-arm, prospective pilot study to investigate the accuracy of Ultrasound in the assessment of the colon when combined with bowel preparation

Acronym
ENPIC

Study objectives
Bowel preparation (oral contrast of gastrografin and low residue diet) before transabdominal ultrasound enhances the identification rate of:
1. Pathology in patients with suspected bowel pathology
2. Identification of the appendix (and any associated pathology of the appendix)

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 06/06/2024, London - Dulwich Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8094; dulwich.rec@hra.nhs.uk), ref: 24/PR /0548

Study design
Non-randomized single-arm prospective pilot study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

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
Accuracy of ultrasound in the assessment of the colon when combined with bowel preparation

Interventions
This is a single-centre, non-randomised, single-arm, prospective pilot study to investigate the accuracy of ultrasound in the assessment of the colon when combined with bowel preparation.

Patients under investigation for possible bowel pathology who are having computed tomography colonography (CTC) investigations will be invited for a single ultrasound examination before their CTC examination. The ultrasound examination/scan will take place in

the same clinical area as the CTC. It is anticipated that participants will be invited to attend an hour before their CTC and have an ultrasound for research purposes that may take up to 30 minutes. The ultrasound procedure and report will be performed following an examination protocol where the findings will be compared to the CTC findings following the CTC scan and report. Statistical analysis will be performed to identify the sensitivity, and specificity of ultrasound compared to CTC.

Timetable
Pending ethical and local approvals recruitment will continue until the end of the recruitment period (24 months following the start date) or when the sample size has been reached, whichever occurs first. The researcher will commence data entry and initial analysis, interpretation, and integration from the first recruited participant and continue to prepare the final report during this period with the final report planned 6 months following the last recruited participant.

Data Accuracy
A full audit trail will be kept for reporting and analysis of both ultrasound and CT scans.

Sample Size
The goal is to meet the sample size estimated through statistical power calculations. This is estimated to be between 268 patients.

Sampling
Convenience sampling will be used, inviting all patients who meet the inclusion criteria.

Public and Patient Involvement (PPI)
The CI has invited the involvement of the Patient Research Ambassador group at the Queen Alexandra Hospital, who have chosen to help researchers with PPI activities. The group think this project is worthwhile and has helped in the writing of the lay summary, the patient invite letter, the patient information leaflets, the recruitment poster and flyer, the interview topic guide and the consent form. The CI also plans to get their help in the dissemination of the results to patients and the wider public to promote the results from the study.

Intervention Type
Procedure/Surgery

Primary outcome measure
The sensitivity of accuracy of transabdominal ultrasound (TAUS) in identifying colonic pathology measured using data collected during TAUS compared with a consensus reference standard (same-day computed tomography colonography [CTC]) at one timepoint

Secondary outcome measures
1. The specificity of ultrasound diagnosis in characterising colonic pathology measured using data collected during TAUS compared with a consensus reference standard (same-day computed tomography colonography [CTC]) at one timepoint
2. The identification rate of the appendix (sensitivity) and any associated pathology of the appendix measured using data collected during TAUS compared with a consensus reference standard (same-day computed tomography colonography [CTC]) at one timepoint
3. Compare ultrasound users:
3.1. Years of experience in ultrasound as self-reported by ultrasound user at baseline
3.2. Type of ultrasound training as self-reported at baseline

Overall study start date
01/06/2024

Completion date
01/05/2027

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Undergoing CTC (for screening or symptomatic indication)
3. Completion of CTC preparation
4. Able to give written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 30; UK Sample Size: 30

Key exclusion criteria
1. Aged <18 years
2. Unable to adequately complete standard CTC preparation
3. Pregnant

Date of first enrolment
01/09/2024

Date of final enrolment
01/08/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Queen Alexandras Hospital
Southwick Hill Road
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PO6 3LY

Sponsor information

Organisation
Portsmouth Hospitals University NHS Trust

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Research organisation

Funder Name
Society of Radiographers

Alternative Name(s)
UK Society of Radiographers, SoR

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Funder Name
College of Radiographers

Funder Name
National Institute for Health and Care 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
Results will be shared nationally at conferences such as the UK Radiology Conference and international conferences such as the European Society of Gastrointestinal and Abdominal Radiology as well as in professional journals.

Intention to publish date
01/05/2027

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date