

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

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<b>Registration date</b> 19/06/2024	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 01/08/2025	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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](mailto:ruth.reeve@porthosp.nhs.uk)

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

Dr Ruth Reeve

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Integrated Research Application System (IRAS)

334186

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

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

## **Study type(s)**

Treatment

## **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(s)**

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

#### **Key secondary outcome(s)**

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

#### **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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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**

United Kingdom

England

**Study participating centre**

**Queen Alexandras Hospital**

Southwick Hill Road

Cosham

Portsmouth

United Kingdom

PO6 3LY

# Sponsor information

## Organisation

Portsmouth Hospitals University NHS Trust

## 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

## 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

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes