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Feasibility of conducting a randomised controlled trial (RCT) comparing invasive (catheter or needle) and non-invasive (clean catch/urine caught in a pot) urine sampling techniques in children under 16 years old with a suspected urinary tract infection

Submission date
10/03/2025

Recruitment status
Recruiting

Registration date
01/04/2025

Overall study status
Ongoing

Last Edited
16/04/2026

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
Internationally, the approach to urine collection varies. For example, in Europe and North America, national guidelines typically favour invasive urine collection methods, given their advantage of much lower rates of bacterial contamination. A UK-based study is required to determine which invasive or non-invasive urine sampling infants, children, and young people should be offered. However, it is not clear if potential participants could be recruited to a randomised controlled trial (RCT) comparing the various urine collection methods and a feasibility study is required to determine if a definitive RCT would be possible and, if so, to inform its design.
The researchers aim to conduct a study of feasibility to assess which participants and interventions should be included in a subsequent randomised controlled trial, explore potential barriers to recruitment and determine the feasibility of randomisation to invasive versus non-invasive urine testing.
This study will be conducted in three parts or work packages.
Work Package 1: a randomised controlled feasibility trial
Work Package 2: a mixed-methods feasibility study
Work Package 3: consensus meeting

Who can participate?
Work Package 1:
Children who are under 16 years old who have a suspected urinary tract infection and cannot provide a midstream urine sample
Work Packages 2 & 3:
1. Parents/guardians of children (0 to under 16 years) and children (aged 7 to under 16 years)

who are approached to participate in Work Package 1 including those who decline randomisation, or who have required urine testing in hospital setting for suspected UTI in the last 3 years.
2. Healthcare practitioners (doctors, nurses, research staff and Allied Health professionals) involved in recruitment to the FROG feasibility trial (Work Package 1) or who are not involved in recruitment to the FROG feasibility trial (WP1).

What does the study involve?
Work Package 1 assesses the feasibility of randomising children to receive invasive (catheter or needle) and non-invasive (clean catch urine in a pot) urine sampling.
Invasive urine sampling involves a catheter inserted into the urethra to collect the urine or a needle placed in the bladder to collect the urine. Non-invasive urine sampling involves catching the urine in a pot while doing a wee.
Children and parents/guardians can consent to share their clinical data, answer brief questions about the sampling method they received, whether randomised or not, and complete a questionnaire 3- 6 months after the urine sample was collected.
Work Package 2 is a mixed methods study including a questionnaire, interviews and focus groups to explore parent/guardian, children's and healthcare professional's views and acceptability of the proposed study and sampling methods.
Work Package 3 is a stakeholder consensus meeting to discuss and describe the feasibility of a final definitive study design.

What are the possible benefits and risks of participating?
Children/parents/guardians will receive an Amazon voucher for taking part in an interview as part of Work Package 2.
There is a risk of discomfort or pain and small risk of damage to the bladder or urethra (where urine comes out of your body) during invasive urine sampling methods as part of Work Package 1.

Where is the study run from?
The Northern Ireland Clinical Trials Unit

When is the study starting and how long is it expected to run for?
September 2024 to June 2026

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

Who is the main contact?
Dr Paula Taylor Miller, FROG@nictu.hscni.net

Contact information

Type(s)
Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
339327

Central Portfolio Management System (CPMS)
60565

National Institute for Health and Care Research (NIHR)
156005

Protocol serial number
B24/28

Study information

Scientific Title
Determining the feasibility of randomising children and young people to invasive and non-invasive urine sampling techniques (FROG): a pragmatic multi-centred randomised controlled feasibility trial and a mixed methods feasibility perspectives study

Acronym
FROG

Study objectives
It is feasible and acceptable to conduct a randomised controlled trial comparing invasive and non-invasive urine sampling techniques in children who are under 16 years old with a suspected urinary tract infection

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/02/2025, North East - Newcastle & North Tyneside 1 Research Ethics Committee (2nd Floor, 2 Redman Place, Stratford, London, E20 1JQ; +44 (0)20 71048061; newcastlenorthtyneside1.rec@hra.nhs.uk), ref: 24/NE/0222

Study design
Pragmatic multicentre randomized controlled feasibility trial

Primary study design
Interventional

Study type(s)
Screening

Health condition(s) or problem(s) studied
Urinary tract infection

Interventions

This is a mixed-methods study consisting of three work packages:
Work Package 1 is a pragmatic multicentre randomised controlled feasibility trial to assess whether it is acceptable to randomise children to receive either invasive (trans-urethral bladder catheterisation or suprapubic aspiration) or non-invasive (clean catch) urine sampling methods.
Work Package 2 is a mixed methods study involving questionnaires, interviews and focus groups with parents, children, young people and health practitioners to explore views on the proposed study.
Work Package 3 is a consensus meeting with key stakeholders to explore the design of a future RCT comparing the effectiveness of invasive versus non-invasive urine sampling in children with suspected UTI.

Work Package 1:
The target population for Work Package 1 are infants, children, and young people (under 16 years of age) requiring an investigation for a suspected UTI who are not toilet trained or cannot provide a caught urine sample in a pot.

During Work Package 1, children and young people under 16 years old will be assessed for eligibility to take part in the randomised feasibility trial. Participants who are eligible to take part will be approached by a member of the research team, who will answer any questions and provide the parent/guardian and child/young person with participant information on the study.

If a participant would like to take part, they will be presented with the consent form, and a member of the research team will then discuss the consent/assent form with the child and parent/guardian.

Work Package 2:
Parent/guardians, children and young people who take part in Work Package 1, including those who decline consent to be randomised, will have an option of taking part in an interview and completing a self-report questionnaire to explore decision-making and acceptability.

Based on previous feasibility studies, the researchers anticipate approximately 50 questionnaires will be completed by parents/guardians. To ensure sample diversity, including parents and children from varied geographic populations and ethnicities, we will use social media and contact charities to recruit parents/guardians of children (0 to under 16 years) and children (aged 7 to under 16 years) who have required urine testing in hospital setting for suspected UTI in the last three years. Approximately 25-35 interviews will be conducted to explore trial feasibility including views on different sampling methods, approach to recruitment and patient-centred outcomes.

Healthcare professionals who were members of the research teams administering sampling procedures in Work Package 1 and wider UK Healthcare practitioners recruited via social media will be invited to take part in a focus group to discuss their views on trial feasibility and design. A total of five focus groups of a maximum of eight healthcare professionals will be conducted.

Work Package 3:
The researchers will conduct an online face-to-face consensus meeting for Work Package 3 bringing together stakeholders from PERUKI, GAPRUKI, PPI, general practice, nursing, ED, inpatient and outpatient settings. The aim is to bring together key stakeholders to review all the data and seek consensus on the design of a future comparative study. A matrix of 12-25 key stakeholders involved in WP1 and WP2, investigator and advisory group contacts and literature searches will be constructed.

Updated 16/04/2026: previously:
The researchers will conduct a face-to-face consensus meeting for Work Package 3 bringing together stakeholders from PERUKI, GAPRUKI, PPI, general practice, nursing, ED, inpatient and outpatient settings. The aim is to bring together key stakeholders to review all the data and seek consensus on the design of a future comparative study. A matrix of 40 key stakeholders involved in WP1 and WP2, investigator and advisory group contacts and literature searches will be constructed.

The methodology used will be similar to that used in previous NIHR HTA-funded studies (e.g., FERN, GASTRIC). Any areas of disagreement and study feasibility will be discussed and agreed upon about a potential study and clinical settings.

Once the potential trial design is established, the researchers will then seek consensus on the overall trial acceptability and feasibility.

A mixed methods study design has been chosen to enable both quantitative and qualitative exploration of the feasibility of the research design, intervention methods, recruitment and consent methods, with qualitative data providing a rich set of data to further explain acceptability data captured in work package 1 in more granular detail further enhancing a family centred approach to RCT design.

This study has been informed by PPI input throughout the application phases, as well as the development of participant-facing materials and study processes.

Timeline:
The total study duration will be 18 months.

Intervention Type
Other

Primary outcome(s)
Work Package 1 Randomised Controlled Feasibility Trial:
Consent to randomisation is measured using the recruitment data at Timepoint 1 (Baseline)

Key secondary outcome(s))
Randomised Controlled Feasibility Trial:
1. Age, gender, ethnicity and basic demographic data are measured using participants' clinical data records at Timepoint 0 (Screening)
2. Patients who are judged unsuitable for the study are measured using eligibility data at Timepoint 0 (Screening)
3. Participants who consent to randomisation to CCU, TUBC or SPA are measured using consent (WP1) and urine sampling methods data at Timepoint 0 (Screening) and Timepoint 2 (Baseline, 1 hour)
4. Participants who consent to randomisation to CCU or TUBC are measured using consent (WP1) and urine sampling methods data at Timepoint 0 (Screening) and Timepoint 2 (Baseline, 1 hour)
5. Participants who consent to randomisation to CCU or SPA only are measured using consent (WP1) and urine sampling methods data at Timepoint 0 (Screening) and Timepoint 2 (Baseline, 1 hour)
6. Participants in each randomised group who received the allocated intervention are measured using adherence to the intervention at Timepoint 3 (2-4 hours following urine sample collection)
7. Contamination by urine collection method is measured using urinalysis results at either

Timepoint 3 (2-4 hours) or Timepoint 4 (within 24 hours of urine sample collection)
8. Safety is measured using adverse events/serious adverse events data at Timepoint 1 (Baseline, 1 hour), Timepoint 2 (2-4 hours), Timepoint 3 (24 hours)
9. Time to collect the urine sample is measured using health resource data at Timepoint 2 (2-4 hours)
10. Pain and distress associated with the urine sample method are measured using the pain and distress scales (FLACC, Wong Baker, SUDS) at Timepoint 2 (2-4 hours)
11. Diagnosis of UTI is measured by urine culture results at Timepoint 3 (within 24 hours of urine sample collection), Timepoint 4 (24 – 72 hours after sample collection)

Completion date
30/06/2026

Eligibility

Key inclusion criteria
Work Package 1: Randomised Controlled Feasibility Trial
1. Child under 16 years of age at presentation
2. Requiring urine testing for suspected UTI
3. Cannot provide a mid-stream urine sample (are not toilet trained)

Work Package 2: Mixed Methods Feasibility Study
Parents and Children:
1. Parents/guardians of children (0 to under 16 years) and children (aged 7 to under 16 years) who are approached to participate in WP1 including those who decline randomisation
OR
2. Parents/guardians of children (0 to under 16 years) and children (aged 7 to under 16 years) who have required urine testing in hospital setting for suspected UTI in the last 3 years

Healthcare Practitioners:
1. Healthcare practitioners (doctors, nurses, research staff and Allied Health professionals) involved in recruitment to the FROG feasibility trial (WP1)
OR
2. UK healthcare practitioners (doctors, nurses, research staff and Allied Health Professionals) not involved in recruitment, screening or conduct of the FROG feasibility trial (WP1)

Work Package 3: Consensus Meeting
1. Parents/guardians of children (0 to under 16 years) and children if feasible (aged 7 to under 16 years) who are approached to participate in WP1 including those who decline randomisation.
OR
2. Parents/guardians of children (0 to under 16 years) and children if feasible (aged 7 to under 16 years) who have required urine testing in hospital setting for suspected UTI in the last three years.
OR
3. Healthcare practitioners (doctors, nurses, research staff and Allied Health Professionals) involved in recruitment to the FROG feasibility trial (WP1)
OR
4. UK healthcare practitioners (doctors, nurses, research staff and Allied Health Professionals) not involved in recruitment, screening or conduct of the FROG feasibility trial (WP1)

Participant type(s)

Health professional, Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
99

Key exclusion criteria
Work Package 1: Randomised Controlled Feasibility Trial
1. A clinical need to collect an immediate invasive urine sample without delay
2. Participants where both methods of invasive urine sampling are deemed inappropriate by the treating clinician or are unavailable
3. Children sedated or admitted to intensive care units at the time of screening
4. Language issues (not overcome with the use of translators and available translated information sheets)
5. Parent or legal representative unavailable to provide informed consent
6. Consent declined

Work Package 2: Mixed Methods Feasibility Study
Parents and Children:
1. Language issues (not overcome with the use of translators and available translated information sheets)
2. Declined consent

Work Package 3: Consensus Meeting:
1. Language issues (not overcome with the use of translators and available translated information sheets)
2. Declined consent

Date of first enrolment
08/06/2025

Date of final enrolment
04/06/2026

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Study participating centre
Royal Belfast Hospital for Sick Children
274 Grosvenor Road
Belfast
Northern Ireland
BT12 6BA

Study participating centre
Leicester Royal Infirmary
Infirmary Square
Leicester
England
LE1 5WW

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

Study participating centre
Birmingham Childrens Hospital
Steelhouse Lane
Birmingham
England
B4 6NH

Study participating centre
University College London Hospital
235 Euston Road
London
England
NW1 2BU

Study participating centre
Bristol Royal Hospital for Children
Children's Emergency Department (E308)

Upper Maudlin Street
Bristol
England
BS2 8BJ

Sponsor information

Organisation
Queen's University Belfast

ROR
https://ror.org/00hswnk62

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be available upon request following the publication of the primary and secondary outcomes. Formal requests for data should be made in writing to Dr Tom Waterfield (Chief Investigator) via the Northern Ireland Clinical Trials Unit (NICTU) (FROG@nictu.hscni.net) and will be reviewed on a case-by-case basis in collaboration with the Sponsor.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	version 1.0	21/11/2025	06/01/2026	Yes	No
Other files		29/01/2026	16/04/2026	No	No
Statistical Analysis Plan		14/01/2026	16/04/2026	No	No
Study website		11/11/2025	11/11/2025	No	Yes