ISRCTN17938841 https://doi.org/10.1186/ISRCTN17938841

Evaluating a new rapid test for urinary tract infections in women

Submission date
08/12/2025

Recruitment status
Not yet recruiting

Registration date
21/01/2026

Overall study status
Ongoing

Last Edited
10/04/2026

Condition category
Urological and Genital Diseases

[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

A urinary tract infection (UTI) is an infection that affects the bladder or waterworks. UTIs are very common, and many people are given antibiotics to help treat them. But not every UTI is caused by bacteria, so antibiotics do not always help. Taking antibiotics when they are not needed can cause side effects and can make antibiotics work less well in the future.

The EVOLUTION study is looking at a new, quick urine test that can be done in the GP surgery or pharmacy. This test can show if bacteria are likely to be causing symptoms and which antibiotic is most likely to work. We want to see if using this new test, alongside usual NHS care, can help reduce unnecessary antibiotic use while still helping people get better safely.
By taking part, patients can help the NHS learn how to give people the right treatment at the right time.

Who can participate?
Patients may be able to take part if:
• They are 18 or older
• They are a woman or were assigned female at birth
• They are registered with a GP surgery or pharmacy that is taking part in the study
• They currently have symptoms of a UTI

What does the study involve?
If a patient chooses to join:
1. They will be asked to give a urine sample.
2. They will complete a short questionnaire about their symptoms.
3. They will be put into one of two groups by chance (like flipping a coin):
o Usual NHS care, or
o Usual NHS care plus the new urine test
4. For the next 28 days, the patient will fill in a very short online diary about how their symptoms change. Most people find this takes only a minute or two.

What are the possible benefits and risks of participating?
While participants may not experience a direct medical benefit, many people find that:

• The new test may help their clinician make a more informed decision about whether antibiotics are needed.
• They feel more involved in their care.
• Tracking symptoms helps them understand how they are improving.
•They like knowing they are helping improve NHS care for others in the future.
• They are helping reduce unnecessary antibiotic use, which protects antibiotics for when they are truly needed.
Risks:
• No test is perfect, so there is a small chance an infection might not be picked up. A GP or pharmacist will always look at both symptoms and any test results. They can still prescribe antibiotics if they think the patient needs them.
• Most people recover well from UTIs with self-care alone.

Where is the study run from?
The study is run from the University of Oxford Nuffield Department of Primary Care Clinical Trials Unit (UK)

When is the study starting and how long is it expected to run for?
April 2026 to December 2027

Who is funding the study?
National Institute for Health and Care Research Health Technology Assessment (NIHR HTA)

Who is the main contact?
Rebecca Lowe (Trial Manager) evolution@phc.ox.ac.uk

Contact information

Type(s)
Public

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Mrs Rebecca Lowe

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Additional identifiers

Central Portfolio Management System (CPMS)
60051

National Institute for Health and Care Research (NIHR)
165318

Integrated Research Application System (IRAS)
338088

Study information

Scientific Title
EVOLUTION: EValuating a nOveL UTI diagnOstic for aNtibiotic stewardship

Acronym
EVOLUTION

Study objectives
1. To determine whether diagnosis including the PA-100 reduces antibiotic prescriptions for UTI, compared to standard of care.
2. To determine whether diagnosis including the PA-100 does not unduly prolong symptoms, compared to standard of care.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 22/12/2025, West Midlands - Solihull Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, United Kingdom; +44 207 1048191; solihull.rec@hra.nhs.uk), ref: 25/WM/0233

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking

Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Diagnostic

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Specialty: General Practice, Primary sub-specialty: General Practice; Health Category: Infection; Disease/Condition: Other diseases of urinary system

Interventions
Following consent, participants will complete a short questionnaire collecting basic information, including age, ethnicity, UTI symptoms, relevant medical history, sexual orientation, geographic location, and any allergies to UTI antibiotics. Suitably trained staff at the GP practice, pharmacy, or other primary care provider will assess eligibility. If eligible, participants will be randomly assigned to either the usual diagnostic process or the diagnostic process with the PA-100 test (test-guided care group). All participants must provide a urine sample on the same day and will receive a leaflet advising on self-care for their UTI.

Participants in the usual diagnostic process will be treated and diagnosed according to standard care, which may involve visual inspection, dipstick testing, or local laboratory testing, depending on local processes. Participants in the test-guided care group will have their urine sample processed using the PA-100 device within 30 minutes of sample collection. Clinicians may use the PA-100 results to diagnose and treat the UTI. Once the test is complete, the clinician will contact the participant to discuss their treatment.

All participants will have a proportion of their urine sample sent to the Specialist Antimicrobial Chemotherapy Unit, Public Health Wales, for reference standard tests.

Follow-up will involve participants receiving a daily link via text or email to complete a web-based symptom diary for the first 14 days, followed by weekly entries until day 28. If any entries are missed, the trial team or site team will contact participants by phone between days 7–12 and 28–36 to provide assistance. Routine health record data will be collected by site staff for up to 28 days after randomisation.

For the qualitative component, some clinicians and participants may be invited to take part in an optional interview, conducted by telephone, online (for example via Microsoft Teams), or in person, to share their experience of participating in the study. In-person interviews with participants will take place in a location that is convenient and comfortable for them, such as a university building, a general practice, or another community setting like a café. Interviews will last up to one hour, and participants may take a break at any point if needed. Interviews will be audio-recorded and sent to a professional transcription company approved by the university.

Permission may also be sought to video record consultations to better understand how treatment decisions are discussed between healthcare professionals and patients. If either the participant or the healthcare provider prefers, the consultation may be recorded using audio only. Audio recording may also be used if it is not practical to set up a video recorder in the room. If participants sought care remotely, permission will be requested to access the recording of their call. Service providers routinely record and store incoming and outgoing calls, and research studies may apply to access these recordings only if the participant agrees and has completed a consent form.

Intervention Type
Other

Primary outcome(s)
1. Antibiotic use is measured as the proportion of participants receiving an antibiotic prescription for UTI within 28 days post-randomisation, captured via the baseline clinician CRF, patient diaries, Day 7 and Day 28 follow-up calls, and medical notes review.
2. Symptom recovery is measured as the proportion of participants who self-report in the online symptom diary/follow up call as being fully recovered, or recovered with only a slight problem or better, on Day 7.

Key secondary outcome(s))
1. Time to recovery measured using participant self-reported data from the online symptom diary over 28 days, including full recovery by Day 7, number of days with moderately bad or worse symptoms, and symptom worsening or progression.
2. Antibiotic consumption for UTI measured as the proportion of participants who self-report, via the symptom diary, having taken antibiotics for their UTI during the 28-day trial period.
3. Antibiotic prescription for UTI at the initial appointment measured using data recorded in the clinician baseline form at Day 0.
4. Recurrence of symptoms measured using participant self-reported data from the online symptom diary over 28 days.
5. Microbiologically confirmed occurrence measured using data recorded in the notes review form for the 28-day trial period.
6. Antibiotic side effects measured as proportion of participants who self-report side effects via the symptom diary over the 28-day trial period.
7. Self-reported consumption of over the counter medications for UTI symptoms measured via the online symptom diary over the 28 day trial period.
8. Number of healthcare contacts with UTI symptoms and UTI-related hospitalisation measured via the online symptom diary over the 28 day trial period and data recorded in the notes review.
9. Test performance of the PA-100 measured via the data recorded in the baseline forms on Day 0 including complete test failure, failure of antibiotic susceptibility.
10. Adherence to test result and prescribing measured by data recorded in the baseline forms on day 0 as well as patient adherence with prescribing decision as measured in the online symptom diary over the 28 day trial period.
11. Diagnostic accuracy is assessed by comparing results from the PA-100 test with laboratory urine culture, measured on Day 0.
12. Clinician experience is measured using interviews and consultation observations on Day 0.
13. Patient experience is measured using interviews carried out during the 28 day trial-period, and consultation observations on Day 0

Completion date
31/12/2027

Eligibility

Key inclusion criteria
1. Assigned Female at birth
2. Aged >= 18 years or above.
3. New presentation of symptoms, which the primary care clinician considers consistent with a suspected uncomplicated UTI.
4. Willing and able to comply with study procedures, including the need to provide a urine specimen within the correct timeframe and has access to email.
5. Willing and able to give informed consent for participation in the study.

Qualitative:
1. Individuals from the participating site qualified to prescribe antibiotics including doctors, nurses, paramedics and pharmacists
2. Other staff from the participating site involved in delivering the PA-100 test (e.g. healthcare assistants)
3. Willing and able to comply with study procedures
4. Willing and able to give informed consent for the interview
5. Participants willing to give consent to an interview with the research team.
6. Clinicians from recruiting sites and participants willing to give consent for their consultation to be audio or video recorded.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
110 years

Sex
Female

Total final enrolment
0

Key exclusion criteria
An individual may not enter the trial if ANY of the following apply:
1. Pregnancy. In cases where it is possible that a patient is pregnant but unaware of it, a pregnancy test will be performed as usual care. However, since this risk assessment is conducted in usual care and in the majority of cases the risk will be low, we have not made a negative pregnancy test a requirement for study entry.
2. On long-term antibiotic treatment

3. Antibiotics taken for UTI in the preceding 7 days or prior treatment with antibiotics for the current UTI episode.
4. Known structural or functional urinary tract abnormalities (e.g. neuromuscular conditions, surgical).
5. Terminal illness
6. Indwelling or intermittent catheterisation
7. Care home resident
8. Previous recruitment to the EVOLUTION trial
9. Immunocompromise due to a relevant condition or due to immunosuppressive therapy.
10. Renal disease
11. Diabetes

Qualitative:
1. Staff not directly involved in antibiotic prescribing or delivering the PA-100 test
2. Staff who decline or are unable to provide informed consent
3. Clinicians from recruiting sites and participants not willing to give consent for their consultation to be audio or video recorded.

Date of first enrolment
27/04/2026

Date of final enrolment
31/12/2027

Locations

Countries of recruitment
United Kingdom

Study participating centre
Southampton
Southampton General Hospital
Tremona Road
Southampton
England
SO16 6YD

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

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 datasets used and analysed during the current study contain potentially sensitive and identifiable patient information under the definitions of UK data protection legislation. Requests for de-identified participant level data collected during this study should be made to the Nuffield Department of Primary Care hosted Datasets Independent Scientific Committee (PrimDISC): primdisc@phc.ox.ac.uk which will include the chief investigator Professor Gail Hayward and representation from the CTU directors. Data will be released following review and approval by PrimDISC of a protocol, statistical analysis plan and the signing of a suitable data sharing agreement.

IPD sharing plan summary
Available on request