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Evaluation of new rapid tests for diagnosing urinary tract infections in GP practices

Submission date
04/05/2023

Recruitment status
No longer recruiting

Registration date
07/07/2023

Overall study status
Ongoing

Last Edited
05/06/2025

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[X] 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 a painful and potentially dangerous condition and will affect almost half of women at least once in their lifetime. The most common treatment is antibiotics, however, antibiotic-resistant UTIs are rising and this is driven further by inappropriate prescriptions of antibiotics.
Current tests for diagnosing UTIs are slow, inaccurate or both. The current standard of care involves using a combination of symptoms, signs and simple dipstick results to predict which women are most likely to have confirmed infection. Better tests, with results available to guide prescriptions, are required to help clinicians avoid prescribing antibiotics to women who do not need them and prescribe the correct antibiotics to those who do. Rapid diagnostic tests for UTIs and their antibiotic resistance are in production, giving clinicians and patients the power to make immediate appropriate treatment decisions.
This study is testing new devices that, hopefully, will quickly tell a GP whether a patient has a UTI – something which is not currently possible. Some of these new devices may also pinpoint which antibiotics may be best suited to treat the infection. To make sure that the devices give reliable information, the researchers will compare the results with those from established tests that can only be done in a specialised laboratory.

Who can participate?
Adult patients registered at a GP practice that is taking part in the study can participate if they are biologically female, aged 18 years or above, and are experiencing symptoms of a suspected urinary tract infection for fewer than 7 days.

What does the study involve?
Potential participants may present to their GP practice suspecting a urinary tract infection (UTI) themselves and may have a urine sample that they take to the GP practice with them. Alternatively, the GP/nurse who they see may suspect that the patient has a UTI. The participant will then be given a Participant Information Sheet (PIS) and questionnaire. This will be presented to them either electronically or on paper. If after reading the PIS the patient is happy to take part, they will sign the Participant Summary Sheet to give consent and they will go on to complete the short questionnaire about their eligibility, information about their sample and their UTI symptoms.

Once the participant has completed the questionnaire, either a fresh or previously collected sample can be used as long as they are processed within the timeframe specified by the manufacturer of the diagnostic tests.
Once the participant has given consent, the questionnaire is completed and a urine sample is given, the participant's active involvement is complete. Any part of the sample that is required for clinical care will be separated and used according to the participant's usual care. This may vary according to the GP practice's usual practice, as according to guidance this may involve visual inspection, dipstick or sending for local laboratory testing. The remaining sample will be used for the research. The answers to the questionnaire will be checked to ensure eligibility by suitably trained staff at the practice. Once eligibility has been confirmed by a member of the study team, the sample will be used for evaluation of the new tests. Part of the remaining sample will be sent to the Specialist Antimicrobial Chemotherapy Unit run by Public Health Wales which will perform reference standard tests.

What are the possible benefits and risks of participating?
There will be no immediate benefit to the participant for taking part in this study, however, it is hoped that the results will help inform better diagnosis of UTI and prescribing of antibiotics in the future. There is no risk involved; however, taking part in the study will take up a small amount of the participant’s time.

Where is the study run from?
University of Oxford, Nuffield Department of Primary Care Health Sciences (UK)

When is the study starting and how long is it expected to run for?
April 2023 to March 2026

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

Who is the main contact?
Rebecca Lowe, Toucan@phc.ox.ac.uk

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
324065

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 56150, IRAS 324065

Study information

Scientific Title
plaTform fOr Uti diagnostiC evAluatioN - TOUCAN

Acronym
TOUCAN

Study objectives
No hypothesis testing will be performed.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/05/2023, London - Central Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (00207 104 8225, +44 (0)207 104 8272, +44 (0)207 104 8286; londoncentral.rec@hra.nhs.uk), ref: 23/LO/0371

Study design
Observational cohort study

Primary study design
Observational

Study type(s)
Diagnostic

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

Interventions

Potential participants may present to their GP practice suspecting urinary tract infection (UTI) themselves and may have a urine sample that they take to the GP practice with them. Alternatively, the GP/nurse who they see may suspect that the patient has a UTI. The participant will then be given a Participant Information Sheet (PIS) and questionnaire.

This will be presented to them either electronically or on paper. If after reading the PIS the patient is happy to take part, they will sign the PSS to give consent and they will go on to complete the short questionnaire about their eligibility, information about their sample and their UTI symptoms. If, however, after reading the PIS they do not wish to take part, they will not complete consent or the questionnaire and should inform the practice that they do not want their sample to be used for research.

Once the participant has completed the questionnaire either a fresh or previously collected sample can be used as long as they are processed within the timeframe specified by the manufacturer of the point-of-care testing (POCT).

Once the participant has given consent, the questionnaire is completed and the sample is given, the participant's active involvement is complete.

Any part of the sample that is required for clinical care will be separated and used according to the participant's usual care. This may vary according to GP practice's usual practice, as according to guidance this may involve visual inspection, dipstick or sending for local laboratory testing. The remaining sample will be used for the research. The answers to the questionnaire will be checked to ensure eligibility by suitably trained staff at the practice.

Once eligibility has been confirmed by a member of the study team, the sample will be used for evaluation of the index POCTs. Part of the remaining sample will be sent to the Specialist Antimicrobial Chemotherapy Unit run by Public Health Wales which will perform reference standard tests.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
The diagnostic performance of novel point-of-care tests for diagnosing urinary tract infection against standard laboratory testing as the reference standard, measured at baseline

Key secondary outcome(s))
1. The symptoms of people who seek help from their GP with suspected UTIs, measured via participant questionnaire completed at baseline
2. Whether and how using the results of a new point-of-care test would result in a change in antibiotic prescribing, measured via the record of prescriptions issued and urine samples collected at the time of consultation (baseline)
3. How often the new tests go wrong and how frequently they give uninterpretable results, measured at baseline

Completion date
31/03/2026

Eligibility

Key inclusion criteria
1. Female
2. Aged 18 years or above
3. Presenting to UK Primary Care with current symptoms that have been present for fewer than 7 days, that the patient or their primary care health professional think are consistent with an uncomplicated UTI
4. Clinician confirms that urine sample for analysis is useful for patient's care
5. Participant is willing to give consent for participation in the study

Qualitative study:
GP practice staff involved in the use of new rapid tests for UTIs willing to give consent to an interview with the research team

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Total final enrolment
1075

Key exclusion criteria
1. Previously recruited to this study
2. Unable to provide a sample that was taken within the timeframe specified by index test developers
3. Unable to understand and complete trial materials in English

Qualitative study:
GP practice staff involved in the use of new rapid tests for UTIs unable to give consent to an interview with the research team

Date of first enrolment
15/06/2023

Date of final enrolment
28/02/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
NIHR CRN: Thames Valley and South Midlands
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
NIHR CRN: Greater Manchester
Address 2nd Floor
Citylabs
Nelson Street
Manchester
United Kingdom
M13 9NQ

Study participating centre
NIHR CRN: North East and North Cumbria
Regent Point
Regent Farm Road
Gosforth
Newcastle upon Tyne
United Kingdom
NE3 3HD

Study participating centre
NIHR CRN: Wessex
Unit 7 Berrywood Business Village
Tollbar Way
Hedge End
Southampton
United Kingdom
SO30 2UN

Study participating centre
NIHR CRN: West of England
Whitefriars
Lewins Mead
Bristol
United Kingdom
BS1 2NT

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
NHS England

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		30/01/2025	03/02/2025	Yes	No

HRA research summary			20/09/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes