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CONDUCT - Collection devices to reduce urine contamination

Submission date	Recruitment status	[X] Prospectively registered
26/09/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/09/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
09/06/2023	Urological and Genital Diseases	

Plain English summary of protocol

Background and study aims
Urinary tract infections (UTIs) are common infections that can affect the bladder, kidneys and the tubes that connect the bladder and kidneys together (the urinary tract). Symptoms include needing to urinate more than usual, pain while urinating, a sudden urge to urinate, feeling that the bladder is never fully empty, abdominal pain, cloudy urine and generally not feeling very well. Anyone can get a UTI but they are more common in women than men. 1 in 10 women see their GP each year because they have a UTI. When someone goes to see their GP with UTI symptoms they may be asked to provide a urine sample which can be sent to the laboratory for urine culture, in order to find out if there are any bacteria present. However, up to 30% of urine samples are contaminated by bacteria which normally live on the body. A contaminated sample cannot rule out infection or prove there is an infection. Another sample will need to be sent, and the delay may increase the length of time a patient experiences symptoms and mean they take extra courses of antibiotics; this could result in infections resistant to antibiotics in the future. If every contaminated urine culture was repeated this would cost over £14 million annually in England and Wales. This study will test whether using urine collection devices to produce urine samples can reduce the chances of contamination. There are two urine collection devices available on the NHS; the Whizaway Midstream and the Peezy. Both claim that they reduce contamination, but this has not been properly tested. The devices are funnel shaped containers which use two different methods to collect the urine sample.

Who can participate?
Women (aged over 18) and presenting to their doctor with symptoms that suggest they have a UTI.

What does the study involve?
Participants are randomly allocated to one of three groups Those in group 1 are given standard Instructions and asked to pass urine into a standard 30ml sterile universal container. Participants in group 2 are given the Peezy Urine collection device to collect their urine sample. Participants in group 3 are asked to provide their urine sample using the Whizaway midstream Urine collection device. All samples collected from each participant is checked for contamination in a

laboratory.
Participants are also asked to complete a questionnaire 14 days after they begin the study and will be contacted by telephone 14-21 days and asked for their views.

What are the possible benefits and risks of participating?
This study does not pose significant risks or benefits to participants associated with taking part.

Where is the study run from?
A number of general practices in the UK

When is the study starting and how long is it expected to run for?
April 2016 to November 2017

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

Who is the main contact?
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2. Dr Gail Hayward

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

2.0

Study information

Scientific Title
The effectiveness and acceptability of two urine collection devices that aim to reduce contaminated urine samples in women presenting with symptoms of urinary tract infection: a three arm trial in UK primary care

Acronym
CONDUCT

Study objectives
To investigate whether use of urine collection devices (UCD), compared to urine collection with standardised instructions, can reduce the proportion of contaminated urine specimens.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East of England - Cambridge East Research Ethics Committee, 08/06/2016, ref: 16/EE/0200

Study design
Single blind individually randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Other

Participant information sheet

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

Interventions
Adult women aged 18 years and over presenting to UK general practice with symptoms attributable to urinary tract infection (UTI), including at least one of dysuria, haematuria or frequency of urination, will be randomised to one of three arms determining how they will provide a urine sample. The arms are:

1. Standard urine collection method: participants will be given a standardised instruction and will be asked to pass urine into a standard 30ml sterile universal container

2. Peezy Urine collection device: a funnel shaped device which channels the early portion of the stream into a sponge and collects the midstream portion in a standard 30ml universal container, with instructions for its use from the manufacturer
3. Whizaway midstream Urine collection device: a funnel shaped device which uses a valve system to discharge the first portion of the stream into the toilet and the midstream into a standard 30ml universal container, with instructions for its use from the manufacturer

Participants will complete a questionnaire 14 days after recruitment and will be contacted by telephone 14-21 days after recruitment.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Peezy Urine collection device, Whizaway midstream Urine collection device

Primary outcome measure
The proportion of contaminated urine specimens; measured as the proportion of samples in each arm reported as a mixed growth following NHS microbiology laboratory urine culture performed according to national standard operating procedures and reported within 7 days of sampling

Secondary outcome measures
To investigate the impact of urine collection devices on:
1. Detection of urine infection using laboratory techniques, measured using the proportion of samples reported as a pure or predominant growth of a known urinary pathogen following urine culture performed according to national standard reporting procedures, and the presence and number of white cells on urine microscopy within 7 days of sampling.
2. The diagnostic accuracy of dipstick urinalysis performed at the time of sample provision for urine infection by reporting sensitivity and specificity of dipstick urinalysis for a pure growth of a known urinary pathogen on urine culture
3. Presence of cells in urine which are suggestive of contamination measured by the presence and number of epithelial cells on urine microscopy reported within 7 days of sampling

Also to investigate:
4. The acceptability of three urine sampling methods to patients using qualitative interviews, which will be ongoing during the trial until saturation of themes is reached
5. The acceptability of three urine sampling methods to primary care professionals from qualitative thematic analysis of focus groups. Focus groups will be performed with primary care professionals at the end of the trial, once results are available for discussion
6. The cost effectiveness and impact on NHS resources measured by:
6.1.Cost per contaminated urine specimen avoided and Cost per QALY gained
6.2. Number of participants requiring one or more further urine culture tests within 14 days
7. Health care utilization and complications in patients using each device compared to standardised usual care measured by the number of participants requiring repeat consultation with the GP or hospital admission for symptoms or complications of UTI within 14 days

8. Morbidity of UTI in patients using a device compared to standardised usual care measured by duration of symptoms in days from index consultation across 14 days form the index consultation

Exploratory additional analyses using combined trial data set:
9. The impact of device use on the types of bacteria identified within 'mixed growth' samples measured as relative amounts of different bacterial species identified by DNA sequencing. This exploratory additional analysis will be performed throughout the period of sample collection and at the end of the trial
10. Whether the patterns of microbial presence in those specimens reported as mixed growth can be reclassified as 'likely infection and 'likely contamination', using patterns of microbial presence identified by DNA sequencing and the correlation of these with patient characteristics (medical history, patient reported features of the UTI and historic and future urine culture results) in order to evaluate a potential reclassification into 'likely infection and 'likely contamination'. This exploratory additional analysis will be performed analysis throughout the period of sample collection and at the end of the trial
11. Whether previous antibiotic use is associated with future urinary tract infection with bacteria which are resistant to antibiotics by evaluating the correlation between resistance profile of urinary pathogens and previous antibiotic usage evaluated by review of the medical records. This exploratory additional analysis will be performed at the end of the trial

Overall study start date
01/04/2016

Completion date
31/12/2018

Eligibility

Key inclusion criteria
Women ≥18 years of age presenting to UK General Practice with symptoms consistent with urinary tract infection.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
1260

Total final enrolment
1264

Key exclusion criteria
The participant may not enter the study if ANY of the following apply:
1. Patients who are currently taking antibiotics or have taken antibiotics in the last 7 days
2. Patients with indwelling catheters or using intermittent self-catheterisation
3. Patients unable to give informed consent
4. Previously recruited to the trial

Date of first enrolment
01/10/2016

Date of final enrolment
20/08/2018

Locations

Countries of recruitment
United Kingdom

Study participating centre
A number of UK general practices.
United Kingdom
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Sponsor information

Organisation
University of Oxford

Sponsor details
Joint Research Office, Block 60, Churchill Hospital
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Sponsor type
University/education

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
National Institute for Health 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
To be confirmed at a later date

Intention to publish date
31/12/2021

Individual participant data (IPD) sharing plan
The current 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?
Results article		24/02/2022	09/06/2023	Yes	No
HRA research summary			28/06/2023	No	No