

# Point of care testing for urinary tract infection in primary care: Stages 3 & 4

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<b>Registration date</b> 10/09/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/11/2020	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Urinary tract infections (UTIs) are common infections that can affect the bladder, the kidneys and the tubes connected to them. The aim of this study is to assess a new way of treating UTIs that involves a Point Of Care Test (POCT). The POCT aims to provide clinicians at the point of care (i.e. within the practice) within 24 hours with a diagnosis of bacterial UTI (or not) and information about whether the UTI is resistant to commonly used antibiotics. This study will determine whether using this POCT results in patients taking antibiotics correctly. The effect of using the POCT will also be assessed on antibiotic use, recovery (duration of symptoms and symptom burden), antibiotic resistance, UTI recurrence, hospitalisation, costs, and cost effectiveness.

### Who can participate?

Non-pregnant women aged 18 and over with symptoms of a UTI

### What does the study involve?

Participants are randomly allocated into two groups. One group receive standard care. The other group have their treatment guided by the POCT test. Participants in the POCT group are asked to provide urine and stool samples at the start of the study and two weeks later, with the urine sample being divided so that half is used for the POCT test and half is sent to be tested in a laboratory. Participants in both groups are asked to fill out a symptom diary each day for 14 days and their medical records are searched for information relevant to UTIs after 3 months. Cost data is also collected.

### What are the possible benefits and risks of patients?

Patients are followed up closely by the research team, and provide data that may improve the quality of care for this common infection. Apart from the time and effort taken to provide data and samples, there are few risks to participants.

### Where is the study run from?

The study is carried out in primary care research networks in Wales, England, Netherlands and Spain

When is the study starting and how long is it expected to run for?  
June 2013 to July 2014

Who is funding the study?  
Seventh Framework Programme

Who is the main contact?  
Nigel Kirby  
kirbyn@cardiff.ac.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Emma Thomas-Jones

**ORCID ID**  
<http://orcid.org/0000-0001-7716-2786>

**Contact details**  
Centre for Trials Research  
College of Biomedical & Life Sciences  
Cardiff University  
7th Floor, Neuadd Meirionnydd  
Heath Park  
Cardiff  
United Kingdom  
CF14 4YS  
+44 (0)29 20687520  
Thomas-jonese@cardiff.ac.uk

**Type(s)**  
Scientific

**Contact name**  
Prof Chris Butler

**ORCID ID**  
<http://orcid.org/0000-0002-0102-3453>

**Contact details**  
Nuffield Department of Primary Health Care Sciences  
Radcliffe Primary Care Building  
Radcliffe Observatory Quarter  
Woodstock Road  
Oxford  
United Kingdom  
OX2 6GG

+44 (0)186 528 9306  
christopher.butler@phc.ox.ac.uk

## **Additional identifiers**

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

14828

## **Study information**

### **Scientific Title**

Point of care testing for urinary tract infection in primary care: Stages 3 & 4 - a randomised controlled trial

### **Acronym**

POETIC Stage 3 and 4

### **Study objectives**

The randomised controlled trial (RCT) aims to quantify the costs and effects of an optimised POCT guided diagnostic and treatment regime for symptoms of uncomplicated UTI. 540 adult female patients from the 4 participating countries will be randomised to either the POCT arm or the standard care (SC) arm. Participants randomised to the intervention arm will have their treatment guided by the Flexicult™ POCT. This strategy will be based upon guidelines on the management of uncomplicated UTI in primary care in participating countries, and use of a POCT to guide antibiotic management. Urine and stool samples will be obtained at presentation (baseline) and two weeks later. The primary outcome will be appropriateness of antibiotic prescribing.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Research Ethics Committee for Wales, 28/02/2013, ref: 12/WA/0394

### **Study design**

Randomised interventional and observational trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

GP practice

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

## Health condition(s) or problem(s) studied

Topic: Primary Care Research Network for England; Subtopic: Not Assigned; Disease: All Diseases

## Interventions

Current interventions as of 12/12/2016:

Intervention arm:

Participants randomised to the experimental intervention arm will have their treatment guided by the Flexicult™ POCT. This POCT is a point of care culture-based approach and involves fresh urine being placed on a special agar plate and the excess urine poured off. The plate is then placed in a simple desktop incubator within the practice, and read approximately 24 hours later. The Flexicult™ system has been used in primary care settings in Denmark for approximately 10 years. POETIC will use new Flexicult™ plates that have been developed by the manufacturer and CE marked (Statens Serum Institut, SSI) to include the antibiotics that are most commonly used in the three participating regions. For patients randomised to the POCT intervention, the result of the test should be available 24 hours after baseline recruitment.

Standard care arm:

Patients randomised to the control arm will receive standard care informed by national guidelines. Clinicians will receive a summary of national guidelines on the management of uncomplicated UTI in primary care (UK, Spain and the Netherlands). Participating clinicians will be provided with the relevant summary for their country, and training in best practice based on their national guidelines. The management of patients who are randomised to the standard care arm will therefore be based upon the management decisions of clinicians who have received training in best practice and a summary of their national guideline(s).

Duration of follow-up was 14-days for patient diary, and medical notes review at 3 months.

Previous interventions:

POCT arm or the standard care (SC) arm.

Flexicult Test, The Intervention is a Flexicult test.

## Intervention Type

Other

## Phase

Not Applicable

## Primary outcome measure

Appropriate antibiotic use, defined as consumption of an antibiotic on day three (or days one or two for fosfomycin) for which a pathogen considered to be causing a UTI isolated in a laboratory was sensitive in vitro, and no antibiotic use by those women who did not have a UTI on laboratory culture

## Secondary outcome measures

Added 12/12/2016:

1. Severity of 11 signs and symptoms, rated by clinicians using a scale of zero (normal/not affected) to six (as bad as it could be, at day 14 and 3 months)
2. Participant-rated severity of symptoms and antibiotic use, recorded in a patient diary on each of the 14 days
3. How patients are able to cope with and understand their illness, measured using the Patient Enablement Instrument at day 14 and 3 months

## Overall study start date

01/06/2013

## Completion date

01/11/2015

# Eligibility

## Key inclusion criteria

1. Women aged 18 years and above presenting with suspected uncomplicated urinary tract infection.
2. Presenting with at least one of three key urinary tract symptoms (dysuria, urgency including nocturia, and frequency)
3. Able to provide informed consent and willing to complete a patient diary.

## Participant type(s)

Patient

## Age group

Adult

## Lower age limit

18 Years

## Sex

Female

## Target number of participants

614 participants (approximately 300 in the UK)

## Key exclusion criteria

Added 12/12/2016:

1. Terminally ill
2. Currently receiving treatment for life-threatening cancer (basal cell carcinoma, for example, excluded)
3. Other severe systemic symptoms, such as high fever, renal angle pain, rigors
4. On long-term antibiotic treatment or have received antibiotics for urinary tract infection within the past four weeks
5. Has had bladder surgery (including cystoscopy) within the past four weeks
6. Known or likely to have significant immune compromise (i.e. known immunodeficiency state, on long-term corticosteroid or chemotherapy treatment, insulin dependent diabetes)

7. Known functional or anatomical abnormalities of the genitourinary tract
8. History of pyelonephritis
9. Known pregnancy
10. Unable to provide a urine sample on the day of first presentation

**Date of first enrolment**

23/07/2013

**Date of final enrolment**

13/08/2014

## **Locations**

**Countries of recruitment**

Netherlands

Spain

United Kingdom

Wales

**Study participating centre**

**South East Wales Trials Unit**

Cardiff

United Kingdom

CF14 4YS

## **Sponsor information**

**Organisation**

Cardiff University (UK)

**Sponsor details**

Heath Park

Cardiff

Wales

United Kingdom

CF14 4XN

**Sponsor type**

University/education

**Website**

<http://www.cardiff.ac.uk/>

ROR

<https://ror.org/03kk7td41>

## Funder(s)

### Funder type

Government

### Funder Name

Seventh Framework Programme

### Alternative Name(s)

EC Seventh Framework Programme, European Commission Seventh Framework Programme, EU Seventh Framework Programme, European Union Seventh Framework Programme, FP7

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

## Results and Publications

### Publication and dissemination plan

The results from the trial have been submitted to a journal and are under review. There will also be a final study report for the funder.

### Intention to publish date

### Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study are available from Professor Chris Butler ([christopher.butler@phc.ox.ac.uk](mailto:christopher.butler@phc.ox.ac.uk)) on reasonable request.

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	25/11/2014		Yes	No
<a href="#">Results article</a>	results	01/04/2018	24/01/2019	Yes	No
<a href="#">Results article</a>	results	23/12/2019	11/11/2020	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No

