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

Submission date
10/09/2013

Recruitment status
No longer recruiting

Registration date
10/09/2013

Overall study status
Completed

Last Edited
11/11/2020

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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?
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Contact information

Type(s)
Scientific

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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
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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) on reasonable request.

IPD sharing plan summary
Available on request

Study outputs

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