POETIC: Point Of carE Testing for urinary tract Infection in primary Care: Study Stages 3 & 4: Randomised controlled trial and post-RCT observational study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Interventional

Summary

ID

NL-OMON39651

Source
ToetsingOnline

Brief title
POETIC

Condition

- Bacterial infectious disorders
- Urinary tract signs and symptoms

Synonym
cystitis, lower UTI, uncomplicated UTI (urinary tract infection)

Research involving
Human

Sponsors and support

Primary sponsor: Cardiff University, contact person Prof. Christopher Butler
Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: antibiotics, primary care, resistance, uncomplicated urinary tract infection

Outcome measures

Primary outcome

The primary outcome will be appropriate antibiotic use on day 3 (with day 1

being the day that the patient consulted with their primary care clinician).

For women who do not have a UTI, appropriate antibiotic use on day 3 will be

defined as no antibiotic use on this day.

Secondary outcome

The secondary objectives are to compare intervention arms with regard to:

* Antibiotic choice in relation to presence of infection and organism

susceptibility and antibiotic spectrum

* Dose and duration of antibiotic prescribed

* Proportion of patients receiving antibiotic prescription

* Adherence to national prescribing guidelines

* Symptoms / recovery

* Recurrence of UTI (within a three month period)

* Patient satisfaction with management

* Antibiotic resistance in urine and stool samples at two week follow up

* Direct / indirect costs

* Cost effectiveness

Study description

Background summary

POETIC is a 4 stage study. This protocol details with stage 3 and 4.

Fifteen percent of community antibiotic prescriptions are for uncomplicated (lower) urinary tract infections (UTI*s). Optimal diagnostic and management strategies for these infections remain unclear. The diagnostic accuracy, of clinical assessment is sub-optimal and as a result many patients are over- or under- managed.

Primary care clinicians are more likely to treat uncomplicated UTI empirically (with an antibiotic agent), without additional testing, if women have symptoms of dysuria and/or frequency. However, 34%- 60% of patients treated with an antibiotic do not have a microbiologically proven UTI and 25% of those with a positive culture are not prescribed antibiotics. This is important in terms of improving outcomes for women with symptoms of UTI. In addition, prescribing without confirmation of a diagnosis contributes to the growing problem of antimicrobial resistance.

Study objective

The overall aim of our study is to evaluate the management of suspected uncomplicated UTI in women presenting in primary care through use of a novel point of care test (POCT, Flexicult). This study is being carried out in 4 European networks: Wales, England, Netherlands and Spain and requires a 4 stage approach. This protocol details with stage 3 and 4.

Within approximately 24 hours the results of this new test will confirm whether or not there is a bacterial infection, the species involved and its resistance profile. If there is an infection the GP will be able to prescribe antibiotics which are most likely to be effective. If no infection is confirmed, the GP can explain the patient why antibiotics are not indicated. Using this new test is expected to improve diagnostic accuracy resulting in less under or over of prescription of antibiotics .

Study design

POETIC Stage 3: Randomised controlled Trial
The RCT aims to quantify the effects and costs of an optimised POCT guided diagnostic and treatment strategy for symptoms of uncomplicated UTI on use of appropriate antibiotics. 540 adult female patients from the 4 primary care research networks will be randomised to either the POCT arm or the standard care (SC) arm. Urine and stool samples will be obtained at presentation

(baseline) and two weeks later. The primary outcome will be appropriate antibiotic use on day 3 (with day 1 being the day that the patient consulted with their primary care clinician). Presenting features and management strategies will be recorded on a case report form by participating clinicians. Urine samples and stool samples (optional) will be collected from all patients, and follow-up will be assessed through the use of a patient symptom diary.

POETIC Stage 4: Post- RCT observational phase
There are important questions that require addressing about the uptake of POCTs in primary care. To answer these a non-randomised pragmatic implementation study will be performed to evaluate the impact of the optimised POCT diagnostic strategy in community practice.
Clinicians from approximately 10 general practices per Network (approximately half of whom participated in the stage 3 RCT) will have the POCT optimised management strategy available for use at their discretion and will audit their use of the POCT by recording anonymised data on patients with suspected UTI, whether or not they used the POCT, and the reasons. A selection of these clinicians and patients will be interviewed to explore expectations and experiences regarding POCT use and barriers and opportunities to uptake of the POCT into routine care.

Intervention

Participants in stage 3 will be randomised (ratio 1:1) to receive the POCT management strategy or the standard care (SC) treatment.
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.
The POCT uses a culture-based approach and involves fresh urine being placed on a special agar plate. The plate is then placed in a simple desktop incubator within the practice, and read approximately 24 hours later. The plate is divided into five segments with different antibiotics and special chromatogenic agar in each segment. This allows for easy assessment of bacterial growth, evaluation of the species present, enumeration, and assessment of resistance to a range of antibiotics.
The new Flexicult* plates that will be used have been developed by the manufacturer (Statens Serum Institut, SSI) and include the antibiotics that are most commonly used in the 4 European networks: Wales, England, Netherlands or Spain.
Patients randomised to the control arm will receive standard care.

Study burden and risks

If patients are assigned to the POCT group (new test), the GP can decide to follow a symptomatic treatment approach (e.g. to give the patient advice to take painkillers) until the results of the POCT are known 24 hours later. If this approach is chosen there is a potential risk the symptoms do not abate over the 24 hours waiting period or get worse. However, in case the symptoms get worse or severe symptoms at consultation the GP can advise to start antibiotics immediately. When the test results become available the GP can contact the patient to advice whether to continue the treatment, to change antibiotics or to stop taking the antibiotics .

After patients have given informed consent, some additional information on symptoms and medical history will be collected. The patient will also be asked to complete a daily symptom and medication use diary for 2 weeks and send an additional urine sample* after two weeks. Therefor participation in the study will take up some additional time.

If patients are randomly assigned to the POCT group (new test), they may be more likely to receive treatment that is likely to benefit them. In addition, by participating in this study they are helping to improve the diagnosis and management of urinary infections, and this may benefit women in the future.

* Patients will also be asked to provide (by post) two stool samples (baseline & after 2 weeks) to determine the effect of antibiotics on the normal bacteria found in the gut. Providing these samples is optional.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Female adult patients age 18 years and above presenting to primary care with at least one of three key urinary tract symptoms (dysuria, urgency including noctural, and frequency) and where the clinician suspects uncomplicated UTI. Patients should be able to provide written informed consent.

Exclusion criteria

Women with one or more of the following are not eligible for inclusion:
* Terminally ill
* Currently receiving treatment for life-threatening cancer (basal cell carcinoma, for example, excluded)
* Other severe systemic symptoms
* On long-term antibiotic treatment or have received antibiotics for urinary tract infection within the past four weeks
* Has had bladder surgery (including cystoscopy) within the past four weeks
* Known or likely to have significant immune compromise (i.e. known immunodeficiency state, on long-term corticosteroid or chemotherapy treatment, insulin dependent diabetes)
* Known functional or anatomical abnormalities of the genitourinary tract
* History of pyelonephritis
* Known pregnancy
* Unable to provide a urine sample on the day of first presentation

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-02-2014
Enrollment:	135
Type:	Actual

Medical products/devices used

Generic name:	FLEXICULT SSI URINARY KIT
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	09-10-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	31-01-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	16-06-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL41212.041.13