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Antibiotic prophylaxis for clean intermittent catheterisation

Submission date	Recruitment status	[X] Prospectively registered
25/10/2013	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/10/2013	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/08/2019	Urological and Genital Diseases	

Plain English summary of protocol

Background and study aims

This study aims to find out whether people who suffer repeated urinary tract infections (UTI) related to the need to empty their bladders intermittently with a fine plastic tube (catheter), a process called clean intermittent self-catheterisation (CISC), benefit from taking continuous daily low-dose antibiotics (antibiotic prophylaxis). We estimate that about 40,000 people in the UK need to use CISC regularly to empty their bladder either because of nerve damage such as multiple sclerosis or because of failure of the bladder muscle to contract, and of these about 25% (10,000 people) suffer frequent UTI. One way to reduce this problem may be to take a small daily dose of antibiotics and the study aims to find out whether such treatment is effective and worthwhile both for the people who suffer the problem and for the NHS. We have assembled a team involving experts in carrying out such a study, and doctors from seven large NHS centres across the UK. The two options to be compared in the trial are firstly, a once daily preventive dose (prophylaxis) of an antibiotic routinely used for this purpose (either nitrofurantoin or trimethoprim or cefalexin), and secondly no prophylaxis. We think that an overall decrease of 20% or more in the frequency of UTI would be large enough for future patients using CISC who get troublesome recurrent UTIs to be routinely offered antibiotic prophylaxis. We will also assess any harm caused by continuous use of antibiotics, particularly side effects for those people taking them and changes in the resistance of bacteria to these antibiotics. We can then work out whether the balance between the benefits and harms make the use of prophylaxis worthwhile to people carrying out CISC and for the NHS as a whole.

Who can participate?

Adults aged 18 or over from across the UK who are regular CISC users can participate if they have suffered at least two UTIs within the past year.

What does the study involve?

Participants are randomly allocated to either receive a once daily preventive dose (prophylaxis) of an antibiotic routinely used for this purpose (either nitrofurantoin or trimethoprim or cefalexin), or no prophylaxis. Participants who are given prophylaxis will be able to swap between the three antibiotics during the 12 months. We will then measure the number of urinary infections suffered by participants in each group and compare the results statistically to see if UTIs are less frequent amongst people taking antibiotic prophylaxis, and if so, whether the

benefit is sufficiently noticeable to be important and useful to patients and the NHS. We will be asking participants in the study to fill in a diary and make sure that they send a urine specimen to the laboratory whenever they feel they have an infection. We will also ask them to complete questionnaires every three months and send routine urine specimens when they join the study and again after six and 12 months together, if separately agreed, with swabs of the perineal area. We will also ask some participants to volunteer to fill in an additional questionnaire and be interviewed by telephone at the end of their participation in the trial. Having to do all this may be quite burdensome for some participants who have other health problems or disabilities. We will ensure by regular contact that members of the research team will be on hand to help when needed and also, in consultation with our patient co-applicant, adapt arrangements where possible to suit individual capabilities. Our team of clinical and scientific experts together with a knowledgeable patient have the skills and experience to successfully complete the study.

What are the possible benefits and risks of participating?
Participants will have closer follow-up than normal and will learn more about their problem from the study information. It is possible that people taking prophylaxis may be better off overall than those who don't but this is very uncertain which is why we are doing the study. The disadvantage of random allocation is that participants will not be able to choose between having, or not having, antibiotic prophylaxis for their recurrent urinary infections; some people may see this as a disadvantage, although it will be emphasised that we do not really know which is the better option. Participants will have to be prepared to have either option for the year of the study.

Where is the study run from?
The study is run from Newcastle by a team from Newcastle University and Newcastle upon Tyne Hospitals NHS Foundation Trust. It is managed by Newcastle Clinical Trials Unit, based in the Medical School at Newcastle University.

When is the study starting and how long is it expected to run for?
The study began in September 2013 and the first patients will be recruited in November 2013. The proposed end date for recruitment is 31 August 2015. The last patient follow-up is expected to complete in February 2017.

Who is funding the study?
The study is funded by the National Institute of Health Research, UK - Health Technology Assessment Programme.

Who is the main contact?
Professor Robert Pickard, the Chief Investigator
Miss Catherine Brennand, the Trial Manager, cath.brennand@ncl.ac.uk

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
2013-002556-32

ClinicalTrials.gov (NCT)
NCT02145338

Protocol serial number
HTA 11/72/01; 15237

Study information

Scientific Title
ANtibiotic Treatment for Intermittent bladder Catheterisation: a randomised controlled trial of once daily prophylaxis (the AnTIC study)

Acronym
AnTIC

Study objectives
Primary objective: To determine whether antibiotic prophylaxis results in a clinically significant reduction in the rate of symptomatic, antibiotic-treated urinary tract infection suffered by people performing intermittent self-bladder catheterisation over 12 months and is cost-effective for the UK NHS.

Secondary objectives: To determine whether use of antibiotic prophylaxis results in better quality of life, better satisfaction with treatment and has an acceptable safety profile including antibiotic stewardship.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/117201
Protocol can be found at : http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0018/81171/PRO-11-72-01.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North East - Sunderland, 01/08/2013, ref:13/NE/0196

Study design
Randomised interventional trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Primary Care Research Network for England, Renal and Urogenital; Subtopic: Not Assigned, Renal and Urogenital (all Subtopics); Disease: All Diseases, Renal

Interventions
Participants are randomised to one of two groups:
Daily antibiotic prophylaxis for a year or to take a separate course of antibiotics only when an active infection occurs.

Follow-up for both study arms is for 12 months.

Study Entry: Single Randomisation only

Intervention Type
Drug

Phase
Not Applicable

Primary outcome(s)
Relative incidence of symptomatic antibiotic-treated UTI between the trial groups; Timepoint(s): 12 months

Key secondary outcome(s))
1. Febrile UTI defined as the primary outcome + presence of a recorded fever of more than 38°C. Confirmed by inspection of primary or secondary healthcare record by research staff
2. Microbiologically-confirmed symptomatic UTI defined as the primary outcome + positive urine culture
3. Antibiotic prescription for asymptomatic UTI without participant-reported or clinician recorded evidence of symptom change
4. Asymptomatic bacteriuria defined as a positive urine culture in the absence of symptoms. Participants will be asked to provide a CSU sent to the central laboratory in provided packaging at baseline prior to randomisation and during asymptomatic periods in months 3, 6, 9 and 12 of their trial participation. They will also be separately consented to provide a CSU six months after completion of trial (18-month timepoint).
5. Hospitalisation due to UTI defined as an unplanned visit to hospital for treatment of a UTI which required at least one overnight stay in hospital. Collected from healthcare record review and checked from participant report or enquiry
6. Participant perception of benefit. We will record and analyse semi-structured interviews with up to 30 participants purposively sampled from both trial arms on completion of their 12-month trial period.
7. Overall satisfaction with allocated treatment strategy. Participants will complete the

treatment satisfaction questionnaire for medication at 12 months as part of their completion of trial questionnaire.
8. Generic health-related quality of life. Participant completion of the SF-36 1-week recall questionnaire at baseline, 3, 6, 9 and 12 months and within the first 2 days of each episode of symptomatic antibiotic-treated UTI prompted by telephone, email or text message

Completion date
28/02/2017

Eligibility

Key inclusion criteria
1. Adult men and women aged ≥ 18 years
2. Completed training of CISC and predicted to continue use for at least 12 months
3. Able to give informed consent for participation in trial
4. Able and willing to adhere to a 12-month follow-up period
5. Have either suffered at least two episodes of symptomatic UTI related to CISC within the last 12 months or, for those previously prescribed prophylactic antibiotics for UTI, have completed a 3-month washout period without antibiotic prophylaxis
6. Able to take a once daily oral dose of at least one of nitrofurantoin, trimethoprim or cefalexin
7. Intermittent catheterisation may be performed by participant, spouse or carer
8. No restriction on type of catheter used

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Age < 18 years
2. In learning phase of CISC
3. Presence of symptomatic UTI; this will be treated and symptoms resolved prior to randomisation
4. Already taking prophylactic antibiotics against UTI and declining 3-month washout period without antibiotic prophylaxis (this will be specifically monitored)
5. Inability to take any one of the three prophylactic antibiotic agents due to multiple drug sensitivities
6. Women who intend to become pregnant during planned period of trial participation or who

are pregnant or who are breastfeeding
7. Previous participation in this study
8. Inability to give informed consent or complete trial documentation

Date of first enrolment
01/11/2013

Date of final enrolment
29/01/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Freeman Hospital
Freeman Road High Heaton
Newcastle upon Tyne
Newcastle Upon Tyne
United Kingdom
NE7 7DN

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)

NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository UK Data Archive.

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2018		Yes	No
Results article	results	01/09/2018		Yes	No
Protocol article	protocol	04/06/2016		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes