Participant Information Sheet

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IRAS Project ID: 206184

Title of Study: A novel antimicrobial urinary catheter for long-term catheter users: a study of its safety

Names of Researchers: Professor Roger Bayston, Mr. Richard Parkinson, Miss Katherine Belfield, Research Nurse

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. Please talk to others about the study if you wish. Ask us if there is anything that is not clear.

Background

Long-term urinary catheter users are at risk of catheter-associated urinary tract infections (CAUTI). This can mean courses of antibiotics, early removal of the catheter, blockage of the catheter, and other serious complications for patients. We have added to the normal urinary catheters three antimicrobial drugs (rifampicin, sparfloxacin, and triclosan) which prevent microorganisms, such as bacteria, from attaching to the catheter to prevent infection. Laboratory studies show that this antimicrobial catheter can prevent infection by the main bacteria that cause CAUTI for 7-12 weeks. In order to bring this catheter to patients, we need to understand if there are any side effects associated with the antimicrobial urinary catheter. The drugs in the catheter have been in use for many years and we do not expect any side effects, but we need your opinion.

What is the purpose of the study?

The purpose of the study is to determine if the addition of three antimicrobials to a silicone urinary catheter produces any side effects when used in patients. This study will also form part of a PhD academic qualification.

Why have I been invited?

You are being invited to take part because you have had a urinary catheter in place for over 28 days and will require another urinary catheter for 28 days or longer. We are inviting 60 participants like you to take part

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you

are still free to withdraw at any time and without giving a reason. This would not affect your legal rights or your treatment.

What will happen to me if I take part?

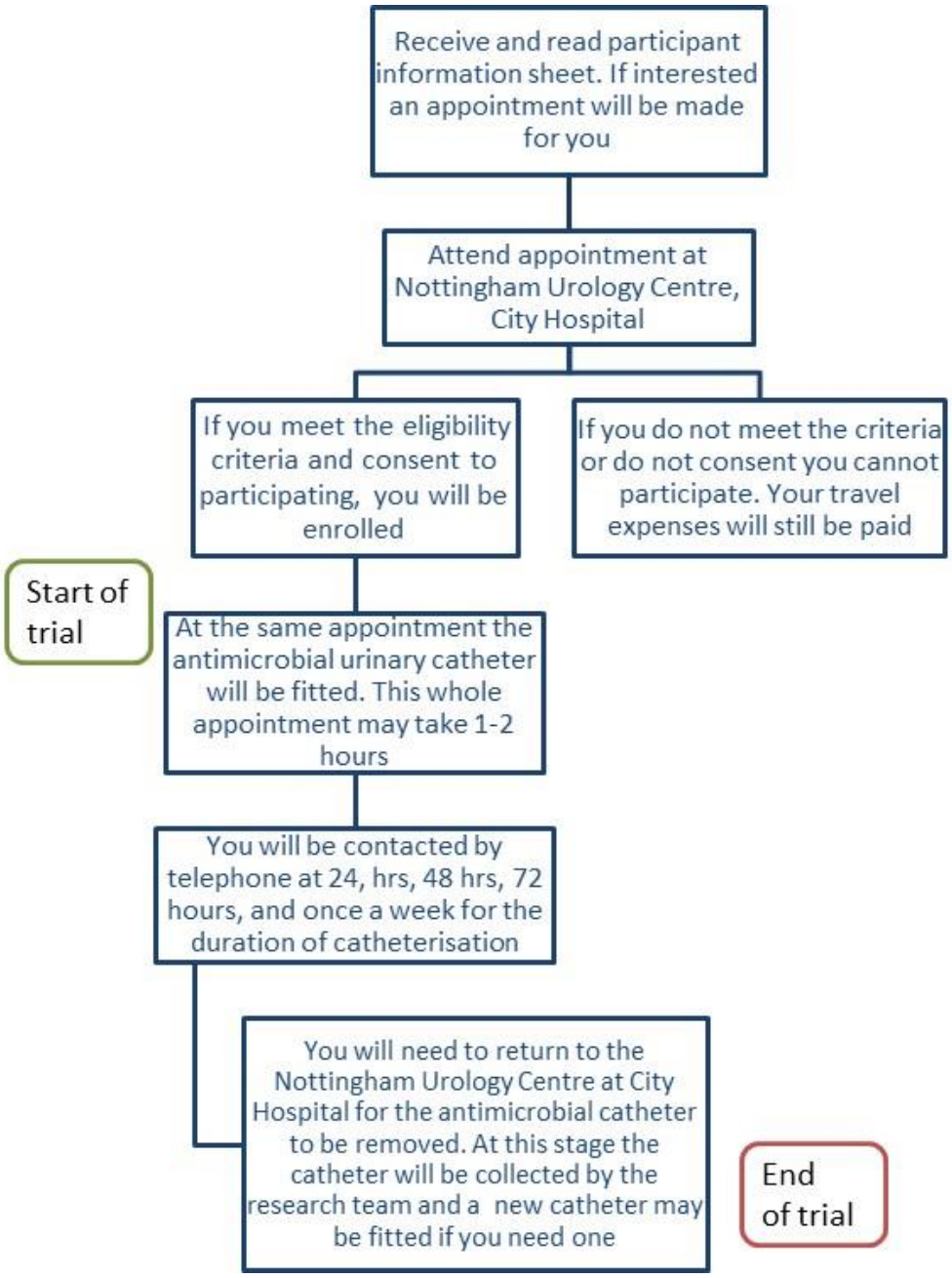
This study does not involve taking any new medicines or drugs. The authorised members of the research team will have to look at your medical notes to ensure you are eligible to be part of the study. If so, at your next catheter insertion date, the antimicrobial urinary catheter will be fitted by the clinical research team at the Urology Centre at City Hospital, Nottingham University Hospitals Trust. If you currently are fitted with a urinary catheter, it will be removed, and the antimicrobial urinary catheter will be fitted in its place. The new catheter will remain in place for your normal catheterisation schedule length (ie if you normally have your catheter changed every 6 weeks, the antimicrobial catheter will remain in place for 6 weeks).

You will be asked to be aware of any sensations or side effects of the antimicrobial urinary catheter unusual to urinary catheterisation. The research nurse will speak to you by telephone at 24 hours, 48 hours, 72 hours, and then once a week for the time the antimicrobial catheter remains in place. Each telephone call may take up to 15 minutes. We will call up to three times on the date to get in touch with you. If the antimicrobial urinary catheter needs to be removed earlier than the expected trial end date, the research nurse will arrange an appointment with you for its removal.

At the first appointment you will also be given a short questionnaire that may take up to 20 minutes to complete. You may choose to complete this at your appointment or complete it at home and return to the research team via a pre-addressed and stamped envelope. The questionnaire will ask questions regarding your current catheter care and also interest in a future randomised controlled trial of the antimicrobial urinary catheter. You will NOT be enrolled into such a trial by answering this questionnaire. The purpose of the questionnaire is to help us determine how many participants in the Nottingham area are eligible and interested in taking part in such a study to plan the future study.

You will need to return to the Urology Centre at City Hospital to have the antimicrobial catheter removed. At this point the antimicrobial catheter will be collected for laboratory analysis, and another normal urinary catheter will, if needed, be fitted.

Please see the following page for a flow diagram of the study:



Expenses and payments

Travel expenses and replacement carer/child-care costs will be offered for any visits incurred as a result of taking part. A taxi can be arranged and paid for in advance if that is convenient. Receipts/invoice/tickets will be required for care arrangements and other travels costs such as car parking fees. If travelling in your own vehicles, please take note of the mileage and travel will be reimbursed at 45p per mile.

What are the possible disadvantages and risks of taking part?

Risks
Several adverse events of urinary catheterisation are well documented, such as risk of CAUTI, leakage of urine around the catheter, blockage of the catheter, or injury to the urethra, bladder or rectum. These are risks of all types of urethral urinary catheterisation. In addition, as the antimicrobial urinary catheter will contain three antimicrobials, which are rifampicin, triclosan, and sparfloxacin, there is a small risk of a local reaction (hypersensitivity) to this antimicrobial catheter. You will be assessed for allergy to the antimicrobials, before you are enrolled in the trial. As with all drugs, it is possible that allergy may result from the antimicrobials in the catheter, and you should inform us of any previous allergic reactions to any of these three drugs. There may also be side-effects associated with their interaction with other medications you are taking. This same technology has previously been shown to be effective in catheters used to treat hydrocephalus (water on the brain) and catheters used for dialysis. The antimicrobials are not new and have been used in clinical practice and in many clinical applications.

Disadvantages
Taking part will also mean taking time out of your normal activities to attend two appointments at the Nottingham Urology Centre, City Hospital, and also speaking on the phone for approximately 15 minutes, once a week. Travel expenses will be paid and we will telephone you so as to not incur extra costs to your phone bill.

What are the possible benefits of taking part?

We cannot promise that the study will help you but the information we get from this study may help the process of regulatory approval for this antimicrobial urinary catheter for use by patients in the community and hospitals, so it will hopefully help patients in the near future. It will also help us calculate how many participants we will need for a future study of the effectiveness (how well it works) of the antimicrobial urinary catheter to prevent infection. The catheter is designed to prevent attachment of bacteria that cause infection, so you may see no signs or symptoms of an infection (CAUTI) during your catheterisation. The catheter also prevents infection by some bacteria that may cause mineral encrustation, which can cause catheter blockage, so you may see reduced catheter blockage. However, this study is not designed to test the effectiveness of the antimicrobial catheter, only to assess the likelihood of side-effects or discomfort.

What happens when the research study stops?

Your involvement in the study will end once you have the antimicrobial urinary catheter removed. The use of another antimicrobial urinary catheter will not be available after the study finishes if you require additional catheterisation. The antimicrobial urinary catheter is currently only available for use as part of this study and cannot be used outside of the trial. If you do require re-catheterisation, at the appointment at which the catheter is removed, a new standard catheter will be fitted for you.

What if there is a problem?

If you have a concern about any aspect of this study at any time, you should ask to speak to the researchers who will do their best to answer your questions. The researchers contact details are given at the end of this information sheet. If you remain unhappy and wish to complain formally, you can do this by contacting the Patient Advice and Liaison Service (PALS):

Visit: Queen's Medical Centre, Derby Road, Nottingham NG7 2UH
B Floor, Main Corridor behind the Main Reception desk at the Derby Road Entrance on B Floor
Phone: 0800 183 0204 or 0115 924 9924 for mobile phone users (Please note that 0800 numbers are now free to call from mobile telephones)
Email: pals@nuh.nhs.uk

Please also be aware that trial participants are covered by appropriate insurance and indemnity provisions. However, there are no special compensation arrangements in place. You may have recourse through NHS complaints procedures.

Will my taking part in the study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, some parts of your medical records and the data collected for the study will be looked at by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

All information which is collected about you during the course of the research will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database. Any information about you which leaves the hospital will have your name and address removed (anonymised) and a unique code will be used so that you cannot be recognised from it.

Your personal data (address, telephone number) will be kept for 4 years after the end of the study so that we are able to contact you about the findings of this study and possible follow-up studies (unless you advise us that you do not wish to be contacted). We would like to keep your personal details for this length of time as securing funding and planning the follow-up studies may be a lengthy process. All research data will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team will have access to your personal data.

Although what you say in the interview is confidential, should you disclose anything to us which we feel puts you or anyone else at serious risk of harm, we may feel it necessary to report this to the appropriate persons.

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights or treatment being affected. If you withdraw then the information collected so far cannot be erased and this information may still be used in the project analysis.

Involvement of the General Practitioner/Family doctor (GP)

We will need to notify your GP of your participation in this research study. This ensures that if you visit your GP during the trial they are aware of any side-effects that may be attributable to the antimicrobial urinary catheter.

What will happen to the results of the research study?

The results will be disseminated, that is communicating the findings, to interested patient groups, published in relevant journals, and will be submitted as part of a PhD thesis. You will not be identified in any report or publication. If you provide us your contact details, we can send you a summary of the trial results and any publications when they are publicly available. The full results will likely be available in May 2018.

Who is organising and funding the research?

This research is being organised by the University of Nottingham in collaboration with Nottingham University Hospitals Trust and is being funded by the National Institute of Health Research Invention for Innovation award programme.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by West Midlands-Edgbaston Research Ethics Committee.

Further information and contact details

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