(to be printed on local headed paper)

IRAS ID: 316986 Ethics ID: 22/SS/0094 Funder ID: NIHR131172 Sponsor ID:RHM GSU0281

Patient Information Sheet – CaDeT Trial

Trial Title: Multicentre Trial of the clinical and cost-effectiveness of a novel urinary catheter design in reducing catheter-associated urinary tract infection compared with the traditional Foley design for adults requiring long-term catheterization.

We'd like to invite you to take part in our research trial. Joining the trial is entirely up to you, before you decide we would like you to understand why the research is being done and what it will involve.

Please read the information below carefully and ask questions if anything is not clear or you would like more information before you decide to take part in the trial. Please feel free to talk to others about the trial, if you wish.

Contents

If you have any questions about this trial, or if you would like to discuss it further, please contact:
<local investigator name> <contact details>
or ctu@soton.ac.uk if you wish to speak to somebody wholly independent from the study team.

Visit the CaDeT trial website for information and watch a short video and listen to an audio recording of this information sheet
www.cadettrial.com

Important things you need to know about CaDeT

1) If you are happy to participate, you will need to complete a consent form before taking part in the trial to confirm that you understand it and agree to take part.
2) You will be put into one of two groups. Your group will be decided by chance: this process is called 'Randomisation'.
3) One group will receive the trial catheter which is called an 'Optitip' catheter. You will have a 50% chance of receiving this. The other group will receive a traditional catheter (known as a 'Foley' catheter).
4) You will receive this catheter at usual catheter changes for 12 months. All other catheter care will stay the same.
5) A researcher will contact you monthly and ask you to report any infections and other symptoms you have had.
6) You will also be asked to complete two questionnaires every 3 months.
   A friend/family member/carer can help you.

Do I have to take part? No. It is entirely up to you if you take part in the trial or not. If you choose not to take part, your routine care will not be affected in any way.

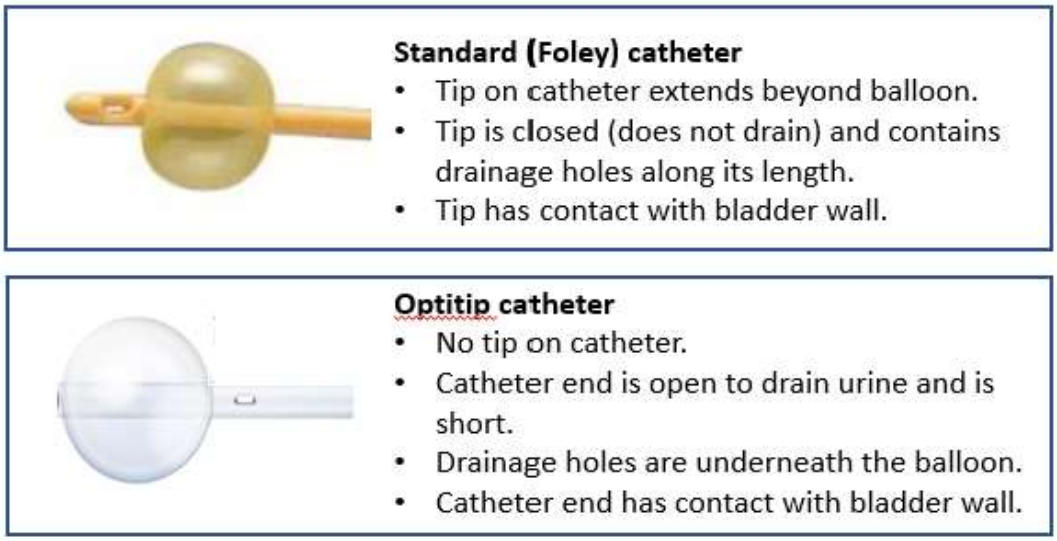
If I start the trial, can I stop if I want to? Yes. If you choose to take part in the trial, you are free to stop at any point without giving a reason, and without affecting the care that you receive.

Why are we doing the CaDeT trial?

Catheters can cause considerable difficulties. Most people using catheters develop an infection involving their urinary tract at least once a year. Catheters can also become blocked, leading to severe pain, urgent catheter change or emergency hospital admission.

A modified catheter, called an Optitip catheter, has design features which are intended to reduce infection and other problems (see diagram below). The Opititp catheter is already used by some patients, however we do not know for certain if it is more effective than a traditional catheter, called a 'Foley' catheter. The CaDeT trial is a randomised trial looking at whether the Optitip catheter reduces the number of Urinary Tract Infections (UTIs) and other catheter related symptoms compared to the Foley catheter. This trial will include around 310 patients.

The Optitip catheter is inserted and removed in the same way as a Foley catheter.



Who is the trial for?

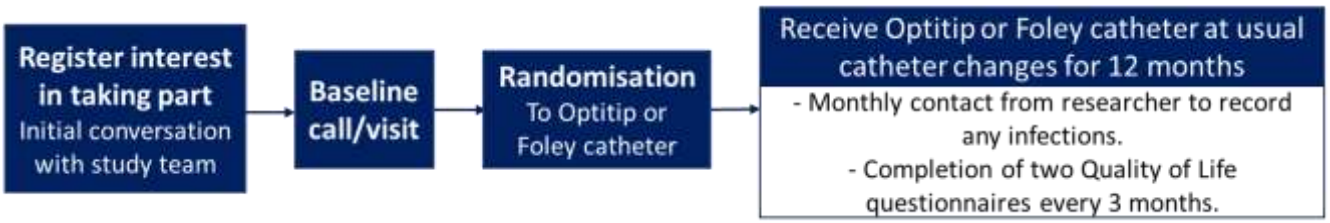
You must:

- Be aged 18 years or older
- Currently be using an indwelling urethral catheter (for any reason) for 28 days or more
- Expect to contine using a catheter for 1 year or more
- Have had 1 or more urinary tract infections (UTIs) associated with your catheter in the past year
- Be living in the community (your own home or residential care, including assisted living)
- Be willing to be randomised to either study arm (Foley catheter or Optitip catheter)
- Be willing and able to provide informed consent

You must NOT:

- Be receiving therapy for bladder cancer
- Be in follow-up for previous bladder cancer
- Be undergoing interventional therapy for prostate cancer
- Had bladder radiotherapy in the past
- Have an unresolved urethral stricture (a narrowing in the tube that carries urine out of the body) or bladder neck stenosis (narrowing of the bladder neck)
- Have Traumatic hypospadias (significant injury to the end of a penis caused by a catheter)
- Be terminally ill

What does taking part involve?



Register interest in taking part

After reading this information sheet, and asking your nurse or doctor any questions, you will need to register your interest in taking part. You can do this by:

- returning your completed reply slip using the pre-paid envelope (it doesn't need a stamp)

or

- registering on the trial website www.cadettrial.com. A friend/family member/carer can help you with this.

If you do not want to take part, we would be grateful if you could select a reason why on the reply slip or website. The standard of care you receive will not be affected in any way.

After you have registered your interest your local trial site will contact you to make sure the CaDeT trial is suitable for you. They will then book a baseline appointment with you. This will usually be completed

by telephone/video call. You can complete the consent form on the trial website, or a paper copy can be posted to you.

Baseline call/visit - Informed consent

During the baseline appointment you will be asked to complete an informed consent form. If you have chosen to use the paper consent form you will need to return this in the pre-paid envelope provided. Your local team will contact you once they have received these to schedule a time to complete the baseline data collection.

We will write to your GP to let them know that you are taking part in the trial, with your permisison.

Baseline call/visit - Data collection

This will take around 30-45 minutes. You will be asked to provide some details about yourself, your catheter use, and how you complete some daily activities. You will also complete two questionnaires:

- EQ-5D-5L – this will ask you about your health-related quality of life.
- ICIQ-LTCqol – this will ask you about your catheter-related quality of life.

The researcher will read the questions to you and record your answers on the questionnaire.

You will be given a paper or electronic diary to record any UTIs and other symptoms associated with your catheter. This diary will help you when a researcher contacts you for the monthly follow-up.

Randomisation

In this trial you will be randomly allocated to receive either the **Optitip catheter OR Foley catheter.** You will be given this at your next planned catheter change. You will continue to receive the assigned catheter (Optitip or Foley) for 12 months. All your other catheter-related care will continue as usual.

If you are allocated to the Optitip catheter group we will send you a supply of catheters to keep at home. We will tell the Community Nurses who complete your catheter changes that you are taking part in the trial. We will also give you a card explaining that you are part of the trial, including which catheter you are allocated to. It can be helpful to have this on you have any unplanned catheter changes.

Follow-up: Monthly call/text/email

A researcher from a CaDeT Co-ordinating hub (at the Southampton Clinical Trials Unit for sites in England, or Glasgow Caledonian University for sites in Scotland) will contact you monthly through the methods you chose at baseline (text, email or telephone call).

The paper/electronic diary you will have received at baseline may help you to recall any symptoms, catherter changes, etc when you answer the monthly follow-up questions.

Text/email

The researcher will send you a text or email with a link to an online platform to answer the monthly follow-up questions. If the researcher does not receive a response from the survey, the researcher will send you a reminder text/email after 1 week and will telephone you after 2 weeks if no response was received.

Telephone

The researcher will send you a text/email to let you know when to expect their telephone call. At the specified time, the researcher will call you and go through the monthly follow-up questions with you.

Researcher will ask:

- If you have had any UTIs in the past month
- If you have had any other symptoms you think are caused by your catheter
- If your catheter has been changed in the past month
- Any medications you took in the past month

The researcher won't be able to give any medical advice, and may share the information you provide with your care team. You should always contact your care team directly if you have any concerns.

At your baseline visit, you there will be the opportunity for a friend/family member/ carer to give their contact details for the monthly follow-ups. The friend/family member/carer can help you when going through the questions of the monthly follow-ups. If you would prefer an interpreter could be used instead of a friend/family member/carer.

Follow-up: Quarterly Questionnaire completion (every 3 months)

Every three months you will complete the two quality of life questionnaires in addition to your usual follow-up. The researcher will read the questions to you and record your answers on the questionnaire.

End of trial

After you have completed the phone call with the researcher at month 12, you will have finished the trial. We will collect information from your Community Nursing records and from your GP Notes. This will include information about your catheter-related care, and any symptoms or medications you had during the trial that are catheter or bladder related (including test results for any infections).

Qualitative interviews (OPTIONAL)

CaDeT Interview

We are interested in your experiences using the Optitip catheter, and of taking part in the trial. We will be looking to interview ~25 participants. The interview will last up to 30 min and will be conducted via telephone or video call. Please note that all interviews will be audio recorded and transcribed.

If you are interested in being interviewed and would like to find out more about the interviews, please agree for your contact details (email address, telephone number, postal address) to be shared with the CaDeT team at Southampton Clinical Trials Unit (SCTU) and the qualitative researcher at the University of Southampton on the Informed Consent Form. We will then send you more information about the interview study. You are free to change your mind at any time if you decide you don't want to be interviewed. Withdrawal from the CaDeT interview study won't affect your participation in the main CaDeT study. Similarly, withdrawal from the EQUATE study interview won't affect your participation in the main CaDeT study.

EQUATE Study Interview

There is the option to express an interest in sharing your views and experences of using digital technology in research (such as elecontric questionnaires) as part of a separate study, called EQUATE. EQUATE is a study led by the University of Southampton which aims to interview those taking part in research to understand how you think digital technology should (or shouldn't) be used so that future research can be easier to take part in. The interview will last for up to one hour over the phone or a video call and as a thank you you will receive a £10 voucher for your time.

Further information will be provided to you if you optionally consent to be contacted by the EQUATE study team, in the CaDeT study Informed Consent Form. Taking part in the EQUATE interview won't affect your participation in the main CaDeT study.

Interview with patients who decline to take part in the CaDeT study

We would like to hear from people who declined to take in the trial. we want to understand your thoughts and feelings about the trial to improve catheter use and the design of future research. The interview will last up to 30 min and will be conducted via telephone or video call. Please note that all interviews will be audio-recorded and transcribed.

If you are interested in being interviewed and would like to find out more about the interviews, please provide your contact details (email address, telephone number, postal address) on the enclosed Reply Slip, so that the qualitative researcher based at the University of Southampton can get in touch with you. We will then send you more information about the interview study. You are free to change your mind at any time if you decide you don't want to be interviewed.

All research in the NHS is reviewed by an independent group of people, called a Research Ethics Committee, to protect your interests. The CaDeT study has been reviewed by the South East Scotland Research Ethics Committee who are happy for the study to proceed. The approval reference is 22/SS/0094. The EQUATE study has been reviewed by London South East Research Ethics Committee who are happy for the study to proceed. The approval reference is 23/PR/0625.

Randomisation: Sometimes we do not know the best way to treat patients. To find out, we need to compare different treatments. We put people into groups and give each group a different treatment; the results are compared to see if one is better. To try to make sure the groups are the same to start with, each patient is put into a group by chance (randomly).

Informed Consent: No one can enter you into the CaDeT trial without your permission. To help you decide if taking part is right for you, the trial nurse/doctor should discuss the trial with you in depth. The most important thing is that you are satisfied you know enough about the trial to make an informed decision. You are free to ask as many questions as you like. In addition, you will be given as much time as you need to make your decision – you should not feel rushed.

If you decide to take part in the CaDeT trial, you will be asked to sign an Informed Consent form, which confirms that you agree to take part. You will be given a copy, a copy will be kept in your medical notes, a copy will be kept in the hospital trial records, and a copy, with your permission, will be sent to the Southampton Clinical Trial Unit via secure e-mail and held securely.

What are the possible benefits and risks of taking part in this trial?

Clinical trials are designed to reduce the risks and increase the benefits to the people who take part, regardless of which treatment they get. However, we cannot guarantee any specific treatment benefits or that there are no risks involved when taking part in a clinical trial.

Possible benefits:

- You will be helping to further our knowledge of the benefits (if any) of the Optitip catheter and this may benefit other catheter users in the future.
- The trial catheter might improve your catheter related symptoms.

Possible risks/disadvantages:

- The trial catheter might not improve your catheter related symptoms.
- You will need to complete data collection calls/visits at baseline, and monthly throughout the trial. You would not need to do this if you were not taking part in the trial.

Other questions you may have about the trial

What are the alternative treatments?

If you prefer not to take part in the CaDeT trial, your doctor/nurse will be able to discuss all treatment options with you. Please be reassured that it is entirely up to you whether or not you take part in the CaDeT trial. If you decide not to take part, the standard of your care will not be affected in any way.

What happens if I change my mind?

You can withdraw from the trial at any time. If you decide to withdraw from the trial you will be given the choice to remain in the trial for follow-up only. This means you can stop using the assigned catheter but would continue with the trial follow-up. If you decide not to stay in the trial for follow-up, your

participation in the trial will end, and you will not be asked to complete any more assessments. Your standard care will not be affected and your decision will not prevent you from taking part in future research studies.

What will happen at the end of the trial?

At the end of the trial, the results will be analysed, but this can take a further 6 months. The results will then be published in a medical journal. No directly identifiable personal data will be used in any reports or publications that come from the CaDeT trial. We will send you a summary of the trial results, unless you have told us that you would prefer not to receive this. The summary will also be available to members of the public on the Southampton Clinical Trials website: www.southampton.ac.uk/ctu/index.page

Will I get paid for taking part in the trial?

You will not receive any monetrary payment for taking part in this trial nor will travelling expenses be reimbursed. There will be no requirement to travel for the trial in most cases. If you take part in the optional CaDeT interview at the end of the trial you will receive a £15 voucher. If you take part in the optional EQUATE study interview at the end of the trial you will receive a £10 voucher.

Can I take part in the trial if I am pregnant?

If you are pregnant, you can enter the CaDeT trial. If you become pregnant during the trial we will record this. You can continue taking part in the trial as usual.

What happens if something goes wrong?

If you decide to take part in the CaDeT trial and feel concerned about any part of the trial at any point, you should contact trial team as soon as possible. The trial team will do their best to help you and answer your questions.

If you wish to complain, or have any concerns about the way you have been approached or treated during the CaDeT trial, please contact the R&D department at University Hospital Southampton NHS foundation Trust by email to sponsor@uhs.nhs.uk. If you remain unhappy and wish to complain formally, you can do this through the normal NHS complaints procedure. Details can be obtained through the following NHS web site:

http://www.nhs.uk/choiceintheNHS/Rightsandpledges/complaints/Pages/AboutNHScomplaints.aspx

Please be aware that if you are harmed as a result of taking part in the CaDeT trial, there are no special compensation arrangements. The University Hopsital Southampton NHS Foundation Trust provides clinical trials indemnity insurance for negligence in its management or design of the trial. NHS Indemnity covers NHS staff, medical academic staff with honorary contracts, and those conducting the trial. NHS Indemnity does not offer no-fault compensation and is unable to agree in advance to pay compensation for non-negligent harm. If you are harmed because of someone's negligence, you may be able to take legal action but you may have to pay your own legal costs.

If you have private medical insurance you may wish to check with your provider before agreeing to take part in this trial to make sure that your participation will not affect your cover.

Who is organising and funding the trial?

This trial is being coordinated by the Southampton Clinical Trials Unit. The trial is funded by the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) Programme. https://www.nihr.ac.uk/funding-and-support/funding-for-research-studies/funding-programmes/health-technology-assessment/

The Sponsor is the University Hopsital Southampton NHS Foundation Trust.

Confidentiality and data protection

Will my details be kept confidential?

Yes. Your participation and the information we collect about you during the course of the research will be kept strictly confidential. University of Southampton will keep identifiable information collected for 10 years after the study has finished.

Only members of the research team and responsible members of the Southampton Clinical Trials Unit and Glasgow Caledonian University Hub may be given access to data about you for monitoring purposes and/or to carry out an audit of the trial to ensure that the research is complying with applicable regulations. Individuals from regulatory authorities (people who check that we are carrying out the trial correctly) may require access to your data. All of these people have a duty to keep your information, as a research participant, strictly confidential.

If you opt to take part in the CaDeT qualitative interviews, your contact details will be shared securely with the CaDeT trial team and the qualitative researcher at Southampton Clinical Trials Unit and stored securely. The qualitative researcher will access your contact details to share information about the qualitative interview with you and to organise the interview. Non-identifiable data, managed by the Southampton Clinical Trials Unit, will be held on servers located within and outside of the UK. Access will be strictly controlled and all current Data Protection Regulations will be abided by. This data is described as 'pseudonymised' because your initials will be stored on the server.

If you've optionally consented to finding out more about the EQUATE study your contact details will be shared securely between the CaDeT trial team to the qualitative researcher based at the University of Southampton.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more below about how we use your information.

You can find out more about how we use your information:

- at www.hra.nhs.uk/information-about-patients/ or scan the QR code
- our leaflet available from https://www.southampton.ac.uk/ctu/about/index.page
- by asking one of the research team
- by sending an email to dataprotection@uhs.nhs.uk
- by ringing us on 023 8120 5154

Your local trial site will collect information from you for this research trial in accordance with our instructions outlined in this patient information sheet. Your local trial site will keep your name and contact details confidential and will not pass this information to the Southampton Clinical Trials Unit, without your informed consent. Your local trial site will use this information as needed, to contact you about the research trial, and make sure that relevant information about the trial is recorded for your care, and to oversee the quality of the trial.

Certain individuals from the Southampton Clinical Trials Unit and regulatory organisations may look at your medical and research records to check the accuracy of the research trial. The Southampton Clinical Trials Unit will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name, or contact details.

With your permission, a copy of your consent will be sent to the Southampton Clinical Trials Unit (where it will be kept securely), to allow confirmation of your consent.

With your permission, we will tell your General Practitioner (GP) that you are taking part in the CaDeT trial. We may also need to talk to your GP about adverse events linked to your catheter. Your medical records will be available to those involved in your clinical care and authorised individuals from the Sponsor or the Sponsor's delegates from the Southampton Clinical Trials Unit, Funder and Regulatory Authorities.

Thank you for taking time to read this information sheet.