



**Information Sheet for General Practitioners**

Dear Dr. [insert name],

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| Patient name: |  | D.O.B: |  |
| Trial ID: |  | Address: |  |
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**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 catheterisation (CaDeT).**

I am writing to inform you of some important changes that we have made to the study, which your patient consented to take part in on <insert date>

The study has been recruiting patients since January 2023. Unfortunately, the study has not recruited enough participants for us to be certain that we will meet the 310 patients that are needed, to make robust and scientific comparisons between the Optitip and the Foley catheter. This means that we are no longer able to effectively answer the question that we initially set out to answer **‘Does the Optitip catheter reduce the number of urinary Tract Infections (UTIs) and other catheter-related symptoms compared to the Foley catheter’.**

Although we are no longer able to answer the question that we set out to answer, there are still some other important research questions in this area that need answering, which we can achieve even with a smaller number of participants recruited. For example, there is a lack of data on the problems associated with long-term catheters. Specifically, there is considerable uncertainty regarding the incidence of UTI and catheter blockage, which can often lead to the high use of out-of-hours community services. Secondly, there is also a gap in knowledge on catheter-associated healthcare costs. There aren’t currently any research studies that can answer these questions. We believe the 78 patients randomised in the study, plus the further 5 patients awaiting randomisation, will provide useful information regarding  these questions.

Your patient was randomised to ‘Optitip/’Foley (traditional)’ on <insert date of randomisation>.

<**only include if randomised to the Optitip Arm/ delete if patient randomised to the Foley**><Since your patient was randomised to the Optitip Arm, they will continue to receive a supply of the Optitip catheter for the 12-month study duration. We recognise that some participants may not have received enough of the Optitip to last them for the 12-month study duration and would need to receive more of this catheter. Please note that whilst we will try our best to provide your patient with more of the Optitip catheter, the supply may be impacted by the availability from the manufacturer LINC Medical, and supply may decrease beyond our control>

The study will remain open to Follow-Up and your patient will still be asked to complete their monthly follow-up questionnaires, for the 12 month duration since the date that they randomised to the study. Your patient will be contacted by a researcher every month asking questions about UTI occurrence, symptoms, antibiotic use, catheter changes and adverse events relating to their catheter use. They will also complete quarterly Quality of Life, and catheter-related quality of life questionnaires. This will be supplemented by quarterly reviews of their community nursing records.

We will contact you to request a review of the participant’s GP records at the end of their trial participation.

I should be grateful if you would notify me of any catheter-related adverse events your patient reports, or you become aware of, during the trial. It would also be extremely helpful if you could please let me know if your patient becomes pregnant during this time. We may also request details of any serious adverse events (SAEs) that may occur during the participant’s trial participation.

<**only include if randomised to the Optitip Arm/ delete if patient randomised to the Foley**>If your patient would like to continue to use the Optitip catheter at the end of the 12-month supply, we have advised for them to speak with the member of their care team responsible for prescribing their catheter. The Optitip catheter is currently available on the UK drug tariff, however, there may be local variation in availability.

I have included a copy of the Patient Information Sheet. If you have any questions about this trial and your patient’s involvement, please get in touch. I have also included a copy of the letter to participating patients explaining the changes being made to the study, and that they remain free to withdraw at any time.

The results of the trial will be published in peer-reviewed journals. A summary will also be available to members of the public on the Southampton Clinical Trial Unit CaDeT website:

www.southampton.ac.uk/ctu/index.page

This trial has been reviewed and received favourable ethical opinion from the South East Scotland REC 02.

For non-urgent queries concerning your patient’s treatment, please contact the Principal Investigator or Clinical Research Nurse as listed below.

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| Principal Investigator: |  | Tel: |  |
|  |  |  |  |
| Clinical Research Nurse: |  | Tel: |  |
|  |  |  |  |
| Contact email address: |  |  |  |

Yours sincerely