(local trust logo)

Information Sheet for General Practitioners

Dear Dr. [insert name],

Patient name: _____ D.O.B: _____

Address: _____

Trial ID: _____

_____

_____

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 that your patient has consented to take part in the CaDeT trial.

This trial aims to determine whether the Optitip catheter provides a clinically effective alternative to the traditional 'Foley' style catheter for reducing catheter-associated UTIs (CAUTIs) and other complications, in adults requiring long-term urinary catheterisation.

The Optitip catheter design provides features not available in the standard 'Foley' that have the potential to reduce rates of UTI for long-term users. The Optitip is available on the UK drug tariff and, despite the lack of evidence and higher cost of device, it is increasingly being used in the NHS.

Your patient was randomised to 'Optitip/'Foley (traditional)' catheter and will receive this catheter type for 12 months from their next planned catheter change.

[If GP is prescribing catheter] – We ask that you prescribe this catheter for your patient for their next planned catheter change on [Date].

Your patient will be told their catheter allocation and the Community Trust research team will also be unblinded to the treatment allocation. 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.

I have included a copy of the Patient Information Sheet that your patient received. If you have any questions about this trial and your patient's involvement, please get in touch.

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

Your patient provided informed consent on……..

Your patient was randomised on……

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.

Principal Investigator: _____ Tel: _____

Clinical Research Nurse: _____ Tel: _____

Contact email address: _____

Yours sincerely,