PReSUTINeB Study

Prevention of Recurrent Symptomatic Urinary Tract Infections in Patients with Chronic Neurogenic Bladder Dysfunction: A Mixed Methods Study

Participant Information Sheet:

Stage 1

**PARTICIPANT INFORMATION FORM**

**Study Number :**

**Centre Number :**

|  |  |
| --- | --- |
|  |  |
| Short Project Title: | **The PReSUTINeB Study - Stage I (participant)** |
| Full Project Title: | Prevention of Recurrent Symptomatic Urinary Tract Infections in Patients with Chronic Neurogenic Bladder Dysfunction: A Mixed Method Study. |
| Name of Researcher: | Senthooran Selvarajah |
| Doc. Version Number: | Version 5 |
| Date: |  |
|  |  |

Introduction

We would like to invite you to take part in a research study which is taking place to prevent and treat urinary tract infections in people who have lost bladder control. This will involve completing some questionnaires.

Please take time to read the following information carefully and discuss it with your partner, family and caregiver if you wish. Please contact us if there is anything that is not clear or if you need more information. Take your time to decide whether you wish to take part.

Thank you for reading this patient information sheet.

Why have I been invited?

You have been chosen because you have had several urinary tract infections (UTIs) over the last year following loss of bladder control. The aim of this project is to contact 24 participants who can share information with us about their experiences of UTI´s.

Do I have to take part?

No you do not have to take part if you do not want to. Taking part in this study is entirely voluntary and it is up to you to decide whether or not to take part.

You do not have to give a reason not to take part. If you decide to take part but later change your mind, you can withdraw at any time without giving a reason.

What is the purpose of the study?

Loss of bladder control involving a problem of the spinal cord, such as spinal cord injury, cauda equina syndrome, multiple sclerosis and transverse myelitis, may lead to serious urinary tract infections.

There is no clear agreement among experts on how to detect urinary tract infection in people who have loss of bladder control. Also many scientific studies disagree on the correct definition of what is a urinary tract infection.

By carefully interviewing patients and by making a thorough literature review, this research project aims to fill the gap in the literature and produce a better definition of urinary tract infection in patients with loss of bladder control (stage 1).

This interview process is stage 1 of a 2 stage process. Stage 2 will determine the practicality of carrying out a larger study using a drug for the prevention of UTIs where there is the potential for you to be invited to take part.

What will happen to me if I take part?

If you decide to take part we will ask you to provide us with some information on your experience of having urinary tract infections. You will undertake an interview and will be asked to fill out questionnaires which will take approximately one hour. The questionnaires can be filled out either online, via mail, or as a direct interview based on your preference). The interviews and questionnaires will be used to collect information about your experience and quality of life in relation to loss of bladder control and urinary tract infections.

These interviews will take place in a private room at The National Spinal Injuries Centre, or at your own home, depending on your preference. Interviews and questionnaires will take place at the same time (1 visit).

The information you give will be used along with information from other participants so that the research team can write and publish a report on the management of urinary tract infections. The voice recording obtained via the digital recorder will be securely stored until the interview has been transcribed fully. Quotes you provide will be made anonymous and may be used within the final report in order to give examples of what was said. Your identity, and that of any people or places you may identify, will be kept anonymous and all names will be replaced with a fictitious name.

The interview will be recorded using a digital recorder by an experienced qualitative researcher and stored on NHS password protected computers. This is to make sure that your views are represented correctly in the study. The information you give will be used along with information from other participants so that the research team can write and publish a report on the management of urinary tract infections. The information recorded via the digital recorder will be stored until the results of all of the transcripts in stage 1 are written up for publication and then the tapes will be destroyed.

As part of the information gathering process you will be asked to give permission for your family member or caregiver to also be interviewed in the study, so that the research team can understand their experience of how you manage urinary tract infections, to enable us to build a complete overview of how the disease is for you. You do not have to authorise your family member or caregiver to provide this information if you do not wish to.

What are the risks and benefits for me if I take part?

There are no immediate disadvantages to taking part. Although you will not benefit directly from taking part in the research the results will help to guide practice in urological health services in the future and importantly improve patient care regarding urinary tract infections.

What if there is a problem?

As a sponsor, the Buckinghamshire Healthcare NHS Trust has approved the design of the current study and remains liable for negligent harm caused during the conduct of the current study and claims arising from it. For more information regarding insurance coverage please ask either your doctor or a research team member named on the last page of this document.

Will the information I give be kept confidential?

All information which is collected about you during the course of the study will be kept strictly confidential. Also your name will not be written on any of the questionnaires making it impossible to connect you with the collected data. Your data will be kept secure on the database using password-protection and will be stored with an anonymous identity number to maintain confidentiality. Data will be stored at the Buckinghamshire Healthcare NHS Trust only, and any information you provide will be seen by the research team only.

Any information about you that leaves the Buckinghamshire Healthcare NHS Trust will have your name and address removed so that you cannot be recognised. Following the Buckinghamshire Healthcare NHS Trust’s policy, all research records are kept for 15 years on the Trust’s promises in secured archives. After this period the documents will be destroyed using the confidential clinical record disposal service.

What will happen to the results of this study?

Once the results of the study have been gathered and analysed, we hope to publish the results in medical journals so that others can read about and learn from them. The investigators will also publish a brief summary of the study results on the research webpage of the Buckinghamshire Healthcare NHS Trust and Stoke Mandeville Spinal Research website. This research project will help us to plan a larger trial to prevent urinary tract infections.

Who is organising and funding the research?

The research is organised by a team of researchers based at Stoke Mandeville Spinal Research at the National Spinal Injuries Centre in Aylesbury. This study is funded by a programme called Research for Patient Benefit (RfPB), which is in turn funded by the Department of Health England. The researchers in this study conduct research on a full-time basis and are paid a fixed salary which is independent of whether you participate in the study or not.

How have patients and the public been involved in this study?

This study is being made with the Spinal Injuries Association (SIA), the Cauda Equina Syndrome (CES) UK Charity, and Transverse Myelitis Society, all of who will be involved in developing the project, protocol and the structure of the questionnaires or surveys that you will be completing as a caregiver.

Who has reviewed and approved the study?

This study has been reviewed and approved by (1) London Harrow Research Ethics Committee B or C, (2) Buckinghamshire Healthcare NHS Trust R&D in conjunction with the National Spinal Injuries Centre Research Board and Stoke Mandeville Spinal Research.

What do I have to do if I decide to take part?

If you are happy to take part we will ask you to sign a consent form and send this to **Dr Senthooran Selvarajah, Stoke Mandeville Spinal Research, National Spinal Injuries Centre, Stoke Mandeville Hospital, Aylesbury, Buckinghamshire, HP21 8AL (contact number 01296 418140).** A copy of this information sheet and the signed consent form will be retained in our trial records. Please contact Dr Selvarajah at any time to learn more about the project.

Who should I contact if I wish to make a complaint?

Any complaint about the way you have been dealt with during the study or any possible harm you might have suffered will be addressed. Please address your complaint to the independent person who is a senior Buckinghamshire Healthcare NHS Trust official:

Denise Watson

Research and Innovation Manager

Research & Development

Buckinghamshire Healthcare NHS Trust

Stoke Mandeville Hospital

HP21 8AL, Aylesbury, Buckinghamshire

United Kingdom

🕾 +44 1296 316259

E: Denise.Watson@buckshealthcare.nhs.uk

How do I get in touch with the research team if I want any further information about the study?

If you have any questions, concerns or complaints about the study, please contact the research team at the following contact number and address.

**Dr Sen Selvarajah, Stoke Mandeville Spinal Research, National Spinal Injuries Centre, Stoke Mandeville Hospital, Aylesbury, Buckinghamshire, HP21 8AL.**

Tel: +44 (0) 1296 418140

Email: [Sen.Selvarajah@buckshealthcare.nhs.uk](mailto:Sen.Selvarajah@buckshealthcare.nhs.uk)

**Thank you very much for reading this.**

**Please discuss this information with your friends or family if you wish.**

Collaborators and Contact Details:

Dr Sen Selvarajah

Research Project Manager

Stoke Mandeville Spinal Research

National Spinal Injuries Centre

Stoke Mandeville Hospital

Buckinghamshire Healthcare NHS Trust

HP21 8AL, Aylesbury, Buckinghamshire

United Kingdom

E-mail: [Sen.Selvarajah@buckshealthcare.nhs.uk](mailto:harriet.allison@buckshealthcare.nhs.uk)

Chief Investigator

Mr Nigel Henderson

Stoke Mandeville Spinal Research

Stoke Mandeville Hospital

National Spinal Injuries Centre

Buckinghamshire Healthcare NHS Trust

HP21 8AL, Aylesbury, Buckinghamshire

E-mail: [Nigel.Henderson@buckshealthcare.nhs.uk](mailto:Nigel.Henderson@buckshealthcare.nhs.uk)

Principal Investigator

Mr Fadel Derry

Consultant Surgeon Spinal injuries

Stoke Mandeville Hospital

Mandeville Road

Buckinghamshire Healthcare NHS Trust

HP21 8AL, Aylesbury, Buckinghamshire

Email: [fadel.derry@buckshealthcare.nhs.uk](mailto:fadel.derry@buckshealthcare.nhs.uk)