PReSUTINeB Study

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

Participant Information Sheet:

Stage 2

**PARTICIPANT INFORMATION FORM**

**Study Number :**

**Centre Number :**

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| Short Project Title: | **The PReSUTINeB Study - Stage 2 (participants)** |
| Full Project Title: | Prevention of Recurrent Symptomatic Urinary Tract Infections in Patients with Chronic Neurogenic Bladder Dysfunction: A Mixed Method Study. |
| Name of Researcher: | Sen Selvarajah |
| Doc. Version Number: | Version 4 |
| Date: |  |
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Introduction

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

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.

The trial we are inviting you to join firstly aims to improve our understanding of the sign(s) and/or symptom(s) associated with a urinary tract infection you may experience throughout this 6 month trial.

In addition to this, antibiotics are regularly used to treat urinary tract infection. However, antibiotic resistance is now a world-wide health concern and it is widely agreed that further research is needed to identify alternative methods of treatment. The use of vaccines is another approach, which works by stimulating the body’s own immune system. One of these vaccines is called Uro-Vaxom® (see below). This part of the clinical study will investigate the ability of Uro-Vaxom® to prevent the number of UTIs you may experience.

What will happen to me if I take part?

If you satisfy the eligibility criteria and your urine sample comes back negative, without the presence of bacteria, you will be enrolled onto the study. A computer will randomly assign which treatment you will receive – Uro-Vaxom® or placebo. A placebo is a substance that has no treatment effect, which is used to show that the experimental drug has a real effect.

You will be provided with enough tablets for the 3 month study, taking one tablet every day before having breakfast. During this visit you will be asked to provide a urine sample so that we can detect if there is any bacteria present and if so, the amount and species of this bacteria. You will also be asked to provide a blood sample on the same day for safety reasons, as well as filling in more than one questionnaire asking questions about your current quality of life. Before you leave you will be provided with a Study Booklet to fill in details about any potential urinary tract infections you may experience during this 6 month trial and vials for the collection of urine samples. Two further appointments will be booked during this visit for you to return to your outpatient department after 1, 3 and 6 months from this current visit. Each visit will take 1 hour.

You can then return to your home. In the event of a suspected urinary tract infection, information given in your Study Booklet will instruct you to contact your GP as this urinary tract infection may need treatment with antibiotics. We also will provide you with a sterile plastic screw-top containers that you can use to collect 2 urine samples (one for the GP and one for the study) and we will ask you to contact your local study coordinator/nurse as soon as possible after the onset of your urinary tract infection, even if this hasn’t been confirmed by your GP. Please note that the study sample will not be used to help your clinical care team to guide your treatment. If you suspect you have an UTI also seek treatment from your GP.

Your study coordinator/nurse will arrange a courier to pick up this urine sample from your home and return it to a microbiology department for testing for purposes of analysis for this trial. You will be asked to enter information about the antibiotics you may have been administered for this urinary tract infection and if you have been administered antibiotics for an illness other than this urinary tract infection during the trial in this Study Booklet.

After 3 months of taking Uro-Vaxom® or placebo every day, you will be asked to return to your outpatient department to give another urine and blood sample, and to fill in three questionnaires relating to your quality of life and experiences of potential urinary tract infections at that time.

After a further three months (six months in total from the beginning of the study), you will be asked to return for one final visit to hand in your Study Booklet with all recorded information about any potential urinary tract infections experienced during the trial and to provide a final urine and blood sample for analysis. You will then be asked to fill in questionnaires relating to your quality of life and experiences of potential urinary tract infections at that time and a questionnaire which will ask questions about how you felt about your participation in this trial.

The total volume of blood that will be collected from you during the study is approximately 40 mL or approximately 7 teaspoons across four sampling visits. Any blood and urine samples you have provided during this trial will be destroyed after each sampling visit and will not be used for analysis in further trials.

Why are you inviting me?

Uro-Vaxom® is specifically intended for people who experience repeated urinary tract infections. The co-investigators of this study – see the names on the last page – work as health professionals and have identified you as a potential participant for the current study. You are being invited because you have the following eligibility criteria:

1. Loss of bladder control due to your spinal Injury (including Cauda Equina syndrome and Transverse Myelitis) or Multiple Sclerosis.
2. At least one year since your current neurological condition was confirmed by your medical doctor and that you are now living in the community.
3. Your current neurological condition has now been stable for the last 9 months, and this has been confirmed by your treating physician.
4. You are aged between 18 to 75 years (Male or Female).
5. You have suffered at least three symptomatic Urinary Tract Infections within the last twelve months, all of which have been treated by antibiotics.
6. You are able provide Written Informed Consent, complete questionnaires, assist all the study visits and provide urine and blood samples during the study procedures.
7. If you are a woman: able and willing to use contraception during study participation.

We aim to recruit 48 patients for this part of the clinical study. The participants will be split 1:1 in terms of the active and placebo arm. Hence 24 participants will be recruited to the active arm and 24 participants to the placebo arm.

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.

A decision not to take part or a decision to withdraw at any time will not affect the healthcare you receive, and will not alter the treatment your doctors have already planned. For instance, if you do happen to get a urinary tract infection, you will still be treated with antibiotics.

What is Uro-Vaxom®?

Uro-Vaxom® is an oral tablet that contains dead bacteria that normally causes the majority of urinary tract infections in people with loss of bladder control. Previous studies show that Uro-Vaxom® can significantly reduce the number of UTIs in otherwise healthy patients, as well as being safe to use.

Do I know whether I will get Uro-Vaxom® or placebo tablets?

No. Using a randomisation process, you will be given either Uro-Vaxom® or placebo tablets and you will not be told what you have received. This is to ensure the trial is completely fair and unbiased, so that results are as accurate as possible. Healthcare staff and the researchers involved in this trial will not know what you have been given. You will not be able to ask for either the Uro-Vaxom® or placebo tablets, or to switch from one tablet to another during the trial.

Will I receive payments and/or reimbursement or expenses?

Yes. You will receive reimbursement of travel expenses to and from your outpatient department on the three organised outpatient visits at month one, month 3 and at month 6 of the study. You will have to arrange your own transport as hospital transport will not be available for participants in this study. Participants can claim reimbursement for travel expenses after each visit to their outpatient department, or at the end of the 6 month trial. Additional costs incurred during this trial cannot be reimbursed.

Risks and Burdens in this study

Patients will be taking a Uro-Vaxom® treatment or dummy (placebo) capsule every morning for 3 months. The safety of Uro-Vaxom® has been reported in previously published clinical trials and these participants had no serious reactions associated with Uro-Vaxom®. The anticipated adverse events as reported in the literature (Uro-Vaxom®,Placebo) in general were very rare:

'Flu'like symptoms (3%)

Headache (2%)

Heartburn (2%)

Soreness or swelling of the vagina (2%)

Diarrhoea (1%)

Nausea/vomiting (1%)

Allergic reaction/rash (1%)

Back pain (1%)

Kidney Pain (less than 1%)

Sleep disorders (less than 1%)

Increased urine frequency (less than 1%)

The study will aim to minimise these risks by the clinical care team closely monitoring the patient throughout the duration of the trial. Please contact your GP if you suffer from one of these events during the study.

Will the information I give be kept confidential?

Yes it will. All information which is collected about you during the course of the study will be kept strictly confidential. Your name will not be written on questionnaires or Study Booklet. The data you give will be kept secure on the database using password-protection and will be stored using a Study 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 data will be destroyed using the confidential clinical record disposal service – subcontracted by the Trust.

We have a number of policies in place to prevent unintentional release of confidential data of study participants; these are listed on the previous page. It will not be possible to identify participants from any published material arising from the study.

Will I be informed if anything changes during the course of the study?

Yes. All study protocol changes and amendments that are deemed to be potentially relevant for participants will be communicated both verbally and in writing. Depending on the urgency of the new information, subjects will be informed either during the next moment of (scheduled) contact or – when urgent – directly by telephone and in writing.

How will the information I provide be used?

Once the results of the study have been gathered and analysed, we hope to publish the results in medical journals, where patient identification will be protected, 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 kind of research will also help us to plan larger trials into prevention of urinary tract infections.

Who is organising and funding the research?

The research is organised by a team of researchers based at four centres in the Thames Valley region; Stoke Mandeville Spinal Research at the Stoke Mandeville Hospital in Aylesbury, Royal Berkshire Hospital in Reading, Rayners Hedge Community Neuro-Rehab in Aylesbury and the Oxford Centre for Enablement in Oxford. This study is funded by a programme called Research for Patient Benefit, 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.

Can I continue to use Uro-Vaxom at the end of the study?

No, this drug is not registered at the moment in the UK. This study will see whether we can test this drug in the future to control urinary tract infections in a much bigger study with many more participants. In the bigger study we hope to test and prove that the drug will have a major benefit to patients with Urinary Tract Infections compared to standard treatments. If the drug is very effective, Vifor Pharma who manufactures Uro-Vaxom® may further explore the benefits of Uro-Vaxom® in the larger study and may ultimately register the product in the UK.

At the end of the study you will receive standard care for your urinary tract infection as provided by your treating physician where you will receive an alternative standard medication such as an antibiotic specific to treat your urinary tract infection.

Who has reviewed and approved the study?

This study has been reviewed and approved by London-Harrow Research Ethics Committee and the Buckinghamshire Healthcare NHS Trust R&D office in conjunction with the National Spinal Injuries Centre Research Board and Stoke Mandeville Spinal Research.

What if there is a problem?

If any harm occurs while you are taking part in this research project, you will have all the rights and protection that normally you have as a National Health Service patient. This includes a National Health Service indemnity policy to cover clinical negligence. If you are harmed due to someone’s’ negligence, then you may have grounds for legal action, but this would have to be proven before compensation is provided. 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 any claims arising from it.

This study will not include no-fault insurance.

For more information regarding medical insurance relating to this clinical trial, please ask either your doctor or a research team member named on the last page of this document.

If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the study, the normal National Health Service complaints procedure are available to you.

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

If you do decide to take part, you must return the letter provided with this information sheet to **Dr Senthooran Selvarajah, Stoke Mandeville Spinal Foundation, National Spinal Injuries Centre, Stoke Mandeville Hospital, Aylesbury, Buckinghamshire, HP21 8AL or via the research nurses at the Reading Royal Berkshire Hospital, Rayners Hedge Community Neuro-Rehab and Oxford Centre for Enablement.** Please enter your name and contact details in this letter to enable the study coordinator for this trial to contact you and give you further details about what to do next. Please also check the eligibility criteria for this trial to decide whether you think you are suitable for this trial.

You must reply within two months of receiving this letter in order to be invited to enter this trial. Please note that we will only be including 48 participants in this trial on a first-come, first-served basis. We also wish to include an even distribution of people using different methods of bladder management, as this is important to this trial and will be taken into account when recruiting the 48 people.

At the screening visit if it is decided you are eligible for this trial, and once you understand study and you are happy to take part, we will ask you to sign a consent form. A copy of this information booklet and the signed consent form will be retained in your hospital case notes.

Your details – including name, date of birth, contact address, hospital number and GP contact details – will be recorded onto the confidential study database. In addition, a series of tests will be run at the screening visit to test whether you meet the eligibility criteria which will involve a general routine medical examination by the site study physician and a urine sample, so that we can detect if there are any bacteria present.

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 below 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

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🕾 +44 1296 316259

E: [Denise.Watson@buckshealthcare.nhs.uk](mailto:Denise.Watson@buckshealthcare.nhs.uk)

Will my GP and spinal injuries consultant be informed about my study participation?

Yes. Unless you explicitly state that you do not want your GP and/or consultant to be informed about your participation in this study, we will send a letter to them outlining the objectives and timeframe of the current study. It is important that your health professionals are aware of other clinical trials that you are participating in. You will not need to inform them yourselves.

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

Your participation in this study is entirely voluntary. You may decide to withdraw your consent for whatever reason at any given point. You may decide not to continue with the project and additionally, if you wish, to have all data collected so far destroyed. Note that a decision to withdraw your consent will not affect your patient care by any means.

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

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

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

Collaborators and Contact Details

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