

# Prevention of recurrent symptomatic urinary tract Infections in participants with chronic neurogenic bladder dysfunction

<b>Submission date</b> 26/10/2015	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 11/05/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 05/08/2019	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English Summary

### Background and study aims

Patients suffering from neurological conditions (conditions of the nervous system) that affect the spinal cord, such as spinal cord injury or multiple sclerosis, may encounter loss of bladder control. This in turn can lead to the development of serious urinary tract infections (UTIs). Although strong evidence is lacking, antibiotics have been widely used for prevention of recurrent UTIs in these patients. However, this approach is now being questioned as antibiotic resistance (in which the bacteria causing the infection are no longer killed by the antibiotics) has become a world-wide health concern. Policy makers recently stressed the importance of research into alternative preventative treatments. For example the use of vaccines, which work by stimulating the body's immune system so that it can fight the infection itself. One of these vaccines is ro-Vaxom®, a pill which contains inactivated traces of the bacteria that normally causes UTIs in patients with loss of bladder control. Previous studies show that Uro-Vaxom® led to a significant reduction of UTIs in otherwise healthy patients, as well as being safe to use. This study is made up of two stages. In the first stage, the aim is to reach an agreement on how best to measure a symptomatic (symptom causing) UTI in patients with loss of bladder function due to spinal cord damage. In the second stage the aim is to conduct a small study on 48 patients into the effectiveness of Uro-Vaxom® in order to find out whether a larger scale study would be possible.

### Who can participate?

Adults with a who have had a neurological condition for at last one year and have had at least three symptomatic UTIs in the last year which have required treatment with antibiotics.

### What does the study involve?

In the first stage of the study, 24 participants attend an interview and are asked to fill out questionnaires about their experiences and quality of life in relation to loss of bladder control and urinary tract infections. In the second stage of the study, 48 participants are randomly allocated to one of two groups. Those in the first group take Uro-Vaxom® capsules once a day for 90 days and those in the second group take an identical looking placebo (dummy pill) once a day for 90 days. At the start of the study and then again after one, three and six months,

participants in both groups complete a number of questionnaires about their experiences of UTIs, as well as providing urine and blood samples. During the six months of the study, all participants keep a study diary, detailing their ongoing experiences of potential UTIs during that time.

What are the possible benefits and risks of participating?

There is a possibility that participants taking the Uro-Vaxom® may benefit from a reduction in the amount of UTIs they have. In the second stage of the study, there is a very small risk that participants taking Uro-Vaxom® may experience side effects including flu-like symptoms, headache or heartburn. There is also a small risk that participants may experience pain or bruising during and after blood testing.

Where is the study run from?

1. Stoke Mandeville Hospital (UK)
2. Oxford Centre for Enablement (UK)
3. Reading Royal Berkshire Hospital (UK)
4. Rayners Hedge Community Neuro-Rehab Unit (UK)

When is the study starting and how long is it expected to run for?

January 2016 to December 2018

Who is funding the study?

National Institute for Health Research (UK)

Who is the main contact?

1. Dr Sen Selvarajah (public)  
sen.selvarajah@buckshealthcare.nhs.uk
2. Dr Julian Taylor (scientific)  
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### **Study website**

<http://www.lifeafterparalysis.com/presutineb/index.htm>

## **Contact information**

### **Type(s)**

Public

### **Contact name**

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### **Contact details**

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**Type(s)**  
Scientific

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## **Additional identifiers**

**EudraCT/CTIS number**  
2015-003913-12

**IRAS number**

**ClinicalTrials.gov number**  
NCT02591901

**Secondary identifying numbers**  
RXQ/648

## **Study information**

**Scientific Title**  
Prevention of Recurrent Symptomatic Urinary Tract Infections in Participants with Chronic Neurogenic Bladder Dysfunction: A Mixed Method Study (The PReSUTINeB Study)

**Acronym**  
The PReSuTINeB Study

**Study hypothesis**  
The aim of this study is to investigate the feasibility of carrying out a larger definitive randomised controlled trial on prevention of symptomatic UTI in patients with chronic neurogenic bladder dysfunction using Uro-Vaxom.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**

**Study design**

Multi-centre prospective randomised placebo-controlled feasibility trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Prevention

**Participant information sheet**

Please see additional files

**Condition**

Urinary tract infections in patients with neurogenic bladder dysfunction

**Interventions**

Stage one:

Participants will be interviewed 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 preference). The interviews and questionnaires will be used to collect information about experiences and quality of life in relation to loss of bladder control and urinary tract infections.

Stage two:

Participants will be randomly allocated (1:1) to the two treatment groups via a central remote computer-based allocation randomisation system provided by the Oxford Clinical Trials Research Unit (OCTRU) using a non-deterministic minimization algorithm to ensure treatment concealment and balanced allocation of participants across the two treatment groups for centre and method of bladder management. The service may be accessed by both telephone (during normal office hours, 8 am to 5 pm), or via a secure randomisation website (24 hours / 7 days a week).

Intervention arm: Participants are treated with Uro-Vaxom® (6mg lyophilised Escherichia coli bacterial lysate per capsule) once a day for 90 days.

Control arm: Participants are treated with a matching placebo once a day for 90 days.

Participants in both groups are provided with a Study Booklet to fill in details about any potential urinary tract infections during the six month study and vials for the collection of urine samples (if a urinary tract infection is suspected). At 1, 3 and 6 months, participants attend follow up appointments lasting for approximately one hour, at which questionnaires are completed and blood and urine samples collected.

**Intervention Type**

Drug

**Phase**

Phase III/IV

**Drug/device/biological/vaccine name(s)**

Uro-Vaxom

**Primary outcome measure**

Study feasibility is determined by recording the recruitment rate for each part of the study and through patient feedback questionnaires completed at baseline, 3 and 6 months

**Secondary outcome measures**

1. Urinary tract infection rate is determined using the study booklet (completed from baseline-six months) and interviews at baseline, 1, 3 and 6 months
2. Compliance to the study drug is measured through examining drug blister packs at 3 months
3. Species and amount of bacteria in urine is measured using a urine culture and sensitivity test at baseline, 1, 3 and 6 months

**Overall study start date**

04/01/2016

**Overall study end date**

31/12/2018

## **Eligibility**

**Participant inclusion criteria**

1. Aged 18 years to 75 years
2. At least one year post onset of neurological condition and now living in the community
3. Neurological status stable for past 9 months, as confirmed by treating physician
4. NBD due to SCI, CES, TM or M
5. Suffered at least three symptomatic UTI within previous twelve months requiring antibiotic course of treatment
6. Able to provide Written Informed Consent and complete study procedures
7. For women able and willing to use contraception during study participation

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

48 (24 participants in stage 1, who are eligible to take part in stage 2)

**Participant exclusion criteria**

1. Having a microbiologically confirmed symptomatic infection at time of randomisation.
2. Use of antibiotics within 14 days of study screening.\*
3. Use of immunosuppressant medication (e.g. anti-rejection drugs, oral or intramuscular steroids or chemotherapy).
4. Involvement in any other IMP related clinical trial within 24 weeks of screening (Screening Visit 1).
5. Surgical intervention of the urinary tract (i.e cystoscopy) 2 months prior to study recruitment.
6. Women who are pregnant or intending to become pregnant or who are breast feeding
7. Known hypersensitivity to any known ingredients in Uro-Vaxom

\*Recruitment can be postponed until antibiotics have not been used for a period of 14 days.

**Recruitment start date**

01/08/2016

**Recruitment end date**

01/03/2017

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre****Stoke Mandeville Hospital**

National Spinal Injuries Centre (NSIC)

Aylesbury

United Kingdom

HP218AL

**Study participating centre****Oxford Centre for Enablement**

Nuffield Orthopaedic Centre

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**Study participating centre**  
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**Study participating centre**  
**Rayners Hedge Community Neuro-Rehab Unit**  
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## **Sponsor information**

**Organisation**  
Buckinghamshire Healthcare NHS Trust

**Sponsor details**  
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**Sponsor type**  
Hospital/treatment centre

**ROR**  
<https://ror.org/037f2xv36>

## **Funder(s)**

**Funder type**  
Government

**Funder Name**

National Institute for Health Research

**Alternative Name(s)**

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## Results and Publications

**Publication and dissemination plan**

Results will be disseminated at the end of each stage of the study respectively  
Plans for the publication will be split in terms of the psychological component of the study for stage 1 to present the analysis regarding signs and symptoms of UTI in relation to patients, healthcare professionals and caregivers. This is intended for the summer of 2017. Once the main part of the clinical finishes with regard to Uro-Vaxom we hope to publish in the autumn of 2018.

**Intention to publish date**

31/12/2019

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Data sharing statement to be made available at a later date

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	version V4	26/02/2016	10/05/2016	No	Yes
<a href="#">Participant information sheet</a>	version V5	01/03/2016	10/05/2016	No	Yes
<a href="#">Protocol article</a>	protocol	16/04/2019	05/08/2019	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No