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

Submission date
26/10/2015

Recruitment status
No longer recruiting

Registration date
11/05/2016

Overall study status
Completed

Last Edited
05/08/2019

Condition category
Urological and Genital Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

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)
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2. Dr Julian Taylor (scientific)
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Additional identifiers

Clinical Trials Information System (CTIS)
2015-003913-12

ClinicalTrials.gov (NCT)
NCT02591901

Protocol serial number
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 objectives
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)
London Harrow Ethics Committee, 02/03/2016, ref: 15/LO/2069

Study design
Multi-centre prospective randomised placebo-controlled feasibility trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
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(s)
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

Key secondary outcome(s))

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

Completion date
31/12/2018

Eligibility

Key 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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key 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.

Date of first enrolment

01/08/2016

Date of final enrolment
01/03/2017

Locations

Countries of recruitment
United Kingdom

England

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
Reading Royal Berkshire Hospital
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United Kingdom
RG15AN

Study participating centre
Rayners Hedge Community Neuro-Rehab Unit
Croft Road
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HP217RD

Sponsor information

Organisation
Buckinghamshire Healthcare NHS Trust

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

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?
Protocol article	protocol	16/04/2019	05/08/2019	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version V4	26/02/2016	10/05/2016	No	Yes

Participant information sheet	version V5	01/03/2016	10/05/2016	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes