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Developmental trial of a new continence device (Vysera valve) that allows bladder emptying by abdominal straining, designed for those with urinary incontinence

Submission date
11/10/2019

Recruitment status
No longer recruiting

Registration date
14/10/2019

Overall study status
Completed

Last Edited
17/01/2020

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
Urinary valves were first introduced in 1986, and have since been shown to be suitable for both male and female patients with indwelling urinary catheters. They are commonly used for patients with intact bladder sensation who can feel when their bladder needs emptying. However, they can be awkward to open, and people with poor hand function often cannot use a valve. We therefore aimed to test whether people could use a different approach to opening the valve, namely raising the pressure in their abdomen ("straining"). To test this, we have designed a valve which stays shut unless sufficient pressure is maintained for long enough. The valve can be positioned using two mountings; one is suitable to put into the end of a catheter, the other can be placed directly into the bladder exit. The valve passively closes the urethra to prevent urine leakage and requires abdominal straining for less than 10 seconds to open and allow bladder emptying. This study has been designed to test the feasibility of the Vyersa valve for first use in humans. We will test it in people with long-term catheters and also people with incontinence after prostate surgery, to ensure that the valve can be opened by people safely and effectively

Who can participate?
Patients over 18 using a catheter for urinary incontinence

What does the study involve?
The valve will be put into position, and we will ask patients to tell us about the experience of having the valve placed. Once it is in position, patients may be asked to allow the bladder to fill up, and when patients feel the need to pass urine, we will check if patients can do so by opening the valve. The valve will be removed, and we will ask patients about the experience of using the valve and having it removed. We will check how patients have been afterwards, including phoning patients after a week. If patients do have any unexpected difficulties, we will give patients contact details to can get in touch if they feel it is needed.

What are the possible benefits and risks of participating?
This is a new design of urinary valve in the very first stages of development. It is not yet fully developed for routine use for patients, so patients will not get immediate benefit from participating in the trial. We hope the valve will become available for patients in the future, based in part on the results of this study.
The risks we feel could apply are; patients might see some blood in the urine for up to a day afterwards (we estimate the risk to be about one in five). patients may experience discomfort sufficient to need simple painkiller tablets (we estimate the risk to be about one in five). patients might get a urine infection which would need treatment with antibiotics (we estimate the risk to be about one in ten).

Where is the study run from?
Bristol Urological Institute, UK

When is the study starting and how long is it expected to run for?
May 2014 to December 2014

Who is funding the study?
1. Vysera Biomedical Ltd
2. Bristol Urological Institute

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
D646-CLN

Study information

Scientific Title
Proof-of-principle trial of the Vysera continence valve to confirm ability to achieve bladder emptying by abdominal straining

Study objectives
A valve can be used to restore continence in people with stress urinary incontinence, but it has to be possible to open it so the user can empty their bladder when required. We hypothesise that raising the abdominal pressure could provide a non-manual approach to opening a urinary valve, with potential application for indwelling catheters or an intraurethral device. The 'Vysera' valve remains closed during short high amplitude spikes but opens when a pre-defined low-amplitude pressure is maintained for a pre-specified duration, allowing sustained abdominal straining to achieve voluntary opening

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/11/2013, NRES Committee West Midlands – South Birmingham Research Ethics Service (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS; +44 (0)207 104 8234; NRESCommittee.westmidlands-southbirmingham@nhs.net), gave ethical approval for a two-

stage proof-of-principle study:
1. Testing the effectiveness of the Vysera valve in a catheter (NRES reference number 10/H1207/94)
2. Its capabilities as an intra-urethral device (NRES reference number 14/WM/1064)

Study design
Non-randomised interventional single-centre cohort study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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

Interventions
This is a non-randomised, cohort study assessing patients with urinary incontinence to determine whether a strain-activated device can be opened by abdominal straining, enabling potential to manage urinary incontinence. Patients volunteered to test the Vysera valve to one of three non-randomized groups.
Group one tested the device attached to the end of a catheter to ascertain whether the valve would open with abdominal straining
Group two were consented to test the device deployment and removal within the urethra under anaesthesia
Group three were consented to test device deployment, device function in terms of capability to open within the urethra using straining, and removal

Allocation to groups was dependent on the time of entry to study.

Data collection by the completion of written case report forms.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Vysera valve

Primary outcome measure
Efficacy of the device (Vysera valve): successfully placed into a catheter or intra-urethrally and be opened with sustained abdominal pressure to allow the patient to void voluntarily. Assessed at time of use.

Secondary outcome measures
Clinician and patient satisfaction with the Vysera valve placement, use and removal process, assessed by interview at the time of use and a follow-up phone call at one week:
1. To evaluate the delivery of the device.
2. To evaluate the retrieval of the device.
3. To evaluate patient tolerance of the device.
4. To evaluate whether urinary containment can be achieved.
5. To assess the level of residual remaining in the bladder post - voiding.
6. To assess the adverse event profile of the device

Overall study start date
01/08/2010

Completion date
01/12/2014

Eligibility

Key inclusion criteria
Stage 1 (Placement and immediate removal of device):
1. 18 years or older attending the clinical site for cystoscopy
2. Recovering from surgery at least 3 months post-surgery
3. Willing and able to give informed consent

Stage 2 (Placement and removal after trial of bladder filling and voiding):
1. Post-prostatectomy male patients 18 years or older, suffering from stress urinary incontinence
2. Undergoing treatment for urinary incontinence or related issues
3. At least 3 months post-surgery
4. Not confined to bed.
5. Adequate bladder / urine storage function
6. Willing and able to give informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

The investigation is designed as a small study of up to 14 subjects

Key exclusion criteria
1. Mentally unstable or cognitively impaired and who are unable to comprehend the informed consent process
2. Renal impairment and/or ureteric reflux
3. Insufficient physical strength to strain determined by urodynamic testing, which is needed to operate the Vysera Urology Catheter Valve for voiding
4. Macroscopic haematuria
5. Symptomatic urinary tract infection (defined as a feeling of malaise, the presence of pyrexia in conjunction with bacteriuria)
6. In the opinion of the investigator are unable to participate
7. Diagnosed detrusor overactivity

Date of first enrolment
14/05/2014

Date of final enrolment
01/12/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Bristol Urological Institute
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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
Vysera Biomedical Ltd

Funder Name
Bristol Urological Institute

Results and Publications

Publication and dissemination plan
The outcome of the trial is intended for publication in a peer-reviewed, open-access journal on conclusion of data collection and analysis

Intention to publish date
01/11/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to commercial sensitivity

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No