An Evaluation of the Vesair® Bladder Control System in the Treatment of Female Subjects with Stress Urinary Incontinence

Published: 29-06-2016
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To evaluate the mechanism of action of the Vesair Bladder Control System for future product development efforts to improve the System, for marketing efforts in the European Union and to provide data for publications.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Urinary tract signs and symptoms
Study type	Interventional

Summary

ID

NL-OMON42956

Source
ToetsingOnline

Brief title
Vesair® Intravesical Pressure Study (VIP Study)

Condition

- Urinary tract signs and symptoms

Synonym
urinary leakage / urethral hypermobility

Research involving
Human

Sponsors and support

Primary sponsor: Solace Therapeutics, Inc.

Source(s) of monetary or material Support: The sponsor will provide funding

Intervention

Keyword: balloon, intravesical pressure, quality of life, stress incontinence

Outcome measures

Primary outcome

Study endpoints:

Phase 1

1. Change in intravesical pressure(s) with the Vesair Balloon from baseline.

2. Change in leak point pressure(s) with the Vesair Balloon from baseline.

Phase 2

1. Patient Global Impression of Improvement of Incontinence (PGI-I)

2. Change in Incontinence Quality of Life (I QOL)

Secondary outcome

NA

Study description

Background summary

Solace Therapeutics, Inc. (the Sponsor) has developed the Vesair® Bladder Control System, a proprietary system that treats the problems of stress urinary incontinence at their source, within the bladder, immediately at the time of the stress event. The Vesair Balloon attenuates transient pressure events within the bladder caused by abdominal pressure changes such as, walking, coughing, or laughing so that the adverse symptoms are reduced or eliminated. The Vesair Bladder Control System was designed to allow for simple, non-surgical insertion and removal of the Vesair Balloon into the female bladder by the physician in his/her office.

Study objective

To evaluate the mechanism of action of the Vesair Bladder Control System for future product development efforts to improve the System, for marketing efforts in the European Union and to provide data for publications.

Study design

Single center study that will enroll 10 subjects. The study is conducted in two phases.

Phase 1 is an acute urodynamics study comparing changes in intravesical pressure during bladder fill in the adult female subjects with stress urinary incontinence, at baseline and within one week after treatment with the Vesair Bladder Control Balloon. Those subjects who choose to keep the balloon in situ following the video urodynamic evaluation(s) enter Phase 2 of the study.

Phase 2 is for those subjects that choose to leave the balloon in place following the urodynamic evaluations. They agree to follow up visits at 6 months, 12, 24, and 36 months.

Quality of Life questionnaires will be collected for all subjects at 6 months, 12 months and annually thereafter through 36 months.
The Solace Balloon will be exchanged at the 12 month visit for all subjects and annually thereafter for an additional 24 month follow up period. Additional balloon exchanges can be made as deemed necessary by the Study Investigator. At the end of the study, subjects will be contacted within 30 days after the last balloon has been removed to confirm final outcome.

Intervention

See study design.

Study burden and risks

Subjects participating in this study will require cystoscopic evaluation and catheterization. The risks associated with these procedures include the following: bladder and/or urethral trauma or irritation; pain; bladder or sphincter muscle spasms; surrounding bruise or collection of blood; blood in the urine; leakage of urine; and urinary tract infections (UTIs). In addition to the events listed above, the anticipated risks associated with the use of the Vesair® Balloon include insertion or removal trauma, urinary symptoms (e.g., urgency, frequency, nocturia), urethral obstruction, stone formation in the bladder, sediment on the Vesair Balloon, bladder mucosal abnormalities, device malfunction or deflation, device being passed out of the bladder, microscopic or gross hematuria, allergic reaction and bacteriuria. There may be risks or side effects that are unknown at this time. The potential benefits

associated with the use of the Solace Balloon outweigh the potential risks.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Women
- Eighteen years of age or older with predominant SUI as evidenced by visual confirmation during stress maneuvers
- Experienced SUI for at least 12 months and attempted and failed prior noninvasive treatment (behavior modification, bladder training exercises, pelvic muscle rehabilitation, biofeedback, electrical stimulation or drug therapy) while incontinent.
- Willing to undergo cystoscopic and video urodynamics procedures required during the initial study period.

Exclusion criteria

- Pregnant or planning pregnancy during the next 12 months
- Morbid obesity, defined as BMI *40
- History of urosepsis, bladder infection (including bladder inflammation or edema), urethral inflammation, urethral edema, urinary tract infection or asymptomatic bacteriuria within the past 3 months
- Recurrent urinary tract infections (* 3 in the past 12 months)
- Prior surgical procedure for incontinence within the past 6 months (including suburethral sling placement and/or removal)
- Urinary incontinence of neurogenic etiology
- History of recurrent (>1) kidney stones, or one within the past 5 years

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-07-2016
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	Vesair Bladder Control System
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	29-06-2016
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	28-09-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL56920.068.16