Solace European Confirmatory Trial: An Evaluation of the Solace Bladder Control System in the Treatment of Female Subjects with Stress Urinary Incontinence.

Published: 20-08-2012
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To confirm previous study results using a Solace Balloon and to support future marketing efforts in the European Union and 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-OMON39390

Source
ToetsingOnline

Brief title
CD 1004 SOLECT TRIAL

Condition

- Urinary tract signs and symptoms

Synonym
Stress Urinary incontinence

Research involving
Human

Sponsors and support

Primary sponsor: Solace Therapeutics, Inc.
Source(s) of monetary or material Support: Solace Therapeutics;Inc.

Intervention

Keyword: Evaluation, Female, Treatment, Urinary

Outcome measures

Primary outcome

Efficacy Endpoints:

The following endpoints will be assessed by assigned treatment and comparison to control at 3 months, and all patients as a single group at 12 months after enrollment:

1. Percent of patients with improvement in Patient Global Impression of Improvement of Incontinence (PGI-I)
2. Percent of patients with improvement in Incontinence Quality of Life (I QOL)
3. Percent of patients with 10 pt. improvement in I-QOL
4. Percent of patients with a reduction in Incontinence Episode Frequency
5. Percent of patients with 50% reduction in Incontinence Episode Frequency
6. Percent of patients with a reduction in provocative pad weight
7. Percent of patients with 50% reduction in provocative pad weight

The above endpoints will also be combined in the form of composite endpoints to reduce the impact of the placebo effect and increase the power of the

statistical analysis. These composite endpoints will be assessed by assigned treatment and comparison to control at 3 months and include:

1. Percent of patients with at least a 50% reduction in provocative pad weight AND Percent of patients with improvement in PGI-I score
2. Percent of patients with at least a 50% reduction in provocative pad weight AND Percent of patients with 10 pt. or greater improvement in I-QOL
3. Percent of patients with at least a 50% reduction in provocative pad weight AND Percent of patients with 50% or greater reduction in Incontinence Episode Frequency

In addition, for all subjects in the Control Group, the study endpoints will be evaluated by comparing the second 3 month period with the Solace Balloon to the first 3 month period without the Solace Balloon.

Safety Endpoints:

The study safety endpoints will include incidence of treatment related mild, moderate or severe adverse events observed over the study assessment period, compared between the Treatment and Control Groups.
In addition, incidence and severity of all adverse events experienced over the entire duration of study device exposure will be assessed.

Secondary outcome

N.A.

Study description

Background summary

The patient will be asked to participate in this study because the patient suffers from involuntary leakage of urine and a condition known as Stress Urinary Incontinence (SUI).

Study objective

To confirm previous study results using a Solace Balloon and to support future marketing efforts in the European Union and provide data for publications.

Study design

Multicenter, prospective, randomized, concurrently controlled and blinded study comparing the Treatment Group to the Control Group with follow up through 36 months. All patients in the Control Group will receive treatment at 3 months.

This study will enroll up to 80 total patients at up to a maximum of 8 study sites. All patients will be randomized to either the Treatment or Control Groups by site, with 2/3 of patients in the Treatment Group and 1/3 of patients in the Control Group and are blinded for the first 6 months of the Study.

Treatment Group: Subjects receive the Solace Balloon throughout the entire study period. Patients are followed through the 12 month follow up period and biannually thereafter to a maximum period of 36 months.

Control Group: Subjects randomized to receive a sham procedure with no Solace Balloon for the first 3 months. After 3 months of data collection, the Control Group have a Solace Balloon inserted and are followed through the 12 month follow up period and biannually thereafter to a maximum period of 36 months.

Study visits will include: Assessment Visit, Treatment Visit, follow up visits at 1, 3, 4, 6, 12, 18, 24, 30 and 36 months for all study subjects. Patients will be consented for all visits, but the 4 month visit is for the Control Group subjects only.

Study endpoints will be assessed for all subjects at 3, 6 and 12 months and annually thereafter through 36 months.

The Solace Balloon will be exchanged at the 12 month visit for all patients 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

N.A.

Study burden and risks

To date, there have been no reports of any serious risks.
Subjects participating in this Study will require visual examination of the bladder and catheterization. The risks associated with these procedures include the following:
- bladder and/or urethral trauma or irritation and/or pain
- bladder or sphincter muscle spasms
- bruising to surrounding tissue
- blood in the urine
- leakage of urine
- urinary tract infections (UTIs)
In addition to the events listed above, the anticipated risks associated with the use of the Solace Balloon System for the insertion or removal of the balloon include:
- insertion or removal trauma
- urinary symptoms (e.g., UTI, blood in urine, pain while urinating and urgency to urinate
- urethral obstruction
- stone formation in the bladder
- abnormalities of the tissue inside the bladder
- balloon malfunction or deflation
- balloon is voided from the bladder during urination
- allergic reaction
- presence of bacteria in urine (bacteriuria)
There may be other risks or side effects that are unknown at this time, and not seen during other studies of this procedure.

Contacts

Public
Solace Therapeutics, Inc.

Newbury Street 135
Framingham, MA 01701-4591
US
Scientific
Solace Therapeutics, Inc.

Newbury Street 135
Framingham, MA 01701-4591
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Has the patient signed a written informed consent form?
2. Is the patient a female 18 years of age or older with stress urinary incontinence that has been documented by visual confirmation of the leakage during stress maneuvers?
3. Has the patient experienced SUI for at least 12 months and attempted and failed prior noninvasive treatment (behavior modification, bladder training exercises, pelvic muscle rehabilitation, biofeedback, electrical or drug therapy) while incontinent?
4. Is the patient available for the minimum study duration of 12 months with a maximum duration of 3 years?
5. Is the patient willing to undergo cystoscopic and urodynamic procedures required during the study period?
6. Has the patient been on stable medication for a minimum of 3 months?
7. Is the patient free of uncontrolled psychiatric illness?
8. Is the patient alert, oriented, mentally competent, and capable of determining their need to void by sensing and responding to an urge to void?
9. Is the patient free of local genital skin infection?
10. Did the patient have a Positive 1-hour Pad Weight (in-office provocative) Test of * 5 g?
11. Is the patient free of impassable urethral strictures, trauma or necrosis?
12. Does the patient have a baseline I-QOL score of *80?

Exclusion criteria

1. Is the patient pregnant or planning to become pregnant during the study period?
2. Does the patient have a life expectancy of < 3 years?

3. Is the patient unwilling to adhere to visit or examination schedules as described in the study protocol?
4. Is the patient non-ambulatory or bedridden or physically unable to complete test exercises?
5. Is there a history of alcoholism or illicit drug abuse within the last year?
6. Is the patient morbidly obese (defined as BMI * 40 kg/m2)?
7. Does the patient have a bladder infection (including bladder inflammation or edema), urethral inflammation, urethral edema, urinary tract infection or asymptomatic bacteriuria observer during study entry and for 3 months prior to study entry?
8. Does the patient have a history of recurrent urinary tract infections (* 2 in the past year)?
9. Does the patient have gross hematuria and/or blood clots in the urine?
10. Does the patient have a history of recent urosepsis (within the previous 30 days)?
11. Has the patient had a prior surgical procedure for incontinence during the past 6 months?
12. Is the patient undergoing or has she undergone biofeedback within three months?
13. Is the patient taking medications for urinary incontinence other than anticholinergics?
14. Is the patient taking other pharmacologic agents that may have a significant effect on bladder function (excluding estrogen and progesterone in menopausal women) and has not been stable on the therapy for at least 3 months or does not intend to continue the medication throughout the trial?
15. Does the patient have urinary incontinence of neurogenic etiology?
16. Does the patient have any neurological disease that could impact bladder function including Parkinson*s disease, multiple sclerosis or post stroke sequelae?
17. Does the patient have a history of interstitial or follicular cystitis?
18. Does the patient have a history of an artificial urinary sphincter?
19. Does the patient have a Cystocele with Stage 3 or higher as scored by the PoP-Q Classification?
20. Is the patient undergoing or anticipating a course of radiation therapy or have severe pelvic fibrosis from previous radiation therapy?
21. Does the patient have a history of kidney stones?
22. Does the patient have uncontrolled diabetes?
23. Does the patient have any active malignancy: a history of any invasive malignancy (except non-melanoma skin cancer), unless the subject has been treated with curative intent and there have been no clinical signs or symptoms of the malignancy for at least 5 years.
24. Does the patient have a prosthetic heart valve or other cardiac condition that puts her at increased risk of subacute bacterial endocarditis?
25. Is the patient unable to tolerate any form of antibiotic?
26. Is the patient taking anticoagulation therapy, other than aspirin?
27. Is the patient immunologically suppressed or immunocompromised?
28. Does the patient have a known allergy to polyurethanes or perfluorocarbons?
29. Does the patient have a Valsalva Leak Point Pressure < 60 cm H20?
30. Does the patient have urinary incontinence due to ISD?
31. Does the patient have post-void residual urine of >100 cc consistently?
32. Does the patient have a urinary flow rate of <5 cc/per second with a minimum voided volume of 150 cc?
33. Does the patient have a bladder capacity of <150 cc or >400 cc?
34. Does the patient have evidence of involuntary detrusor contractions?
35. Does the patient have hypersensitivity to cytoscopy or other urethral manipulations?

36. Does the patient have a urethral abscess, fistula, or other anatomic abnormalities, which would interfere with device placement?

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-11-2012
Enrollment:	45
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	20-08-2012
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	03-10-2012

Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	18-04-2013
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	10-07-2013
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	31-10-2013
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	01-09-2014
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	NL40973.068.12
Other	Pending