Virtue male Sling European Study

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The Virtue male sling study in Europe is designed to assess efficacy and safety of the Virtue® Male Sling.

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

Summary

ID

NL-OMON39719

Source
ToetsingOnline

Brief title
Virtue study

Condition

- Urinary tract signs and symptoms

Synonym
Stress urinary incontinence or unvoluntary loss of urine

Research involving
Human

Sponsors and support

Primary sponsor: Coloplast BV
Source(s) of monetary or material Support: Coloplast Corp.

Intervention

Keyword: efficacy, male sling, safety, Virtue

Outcome measures

Primary outcome

The primary end point of this study is to assess the efficacy and safety of the surgical procedure based on improvement in 24-hour pad weight and adverse event reporting in the Virtue® Male Sling European Study at 12 months post implant. Secondary objectives will assess subject satisfaction, patient reported pad use, and change in 24 hour pad weight through 36 months.

The primary end point will be based on the following endpoints after the 12 months follow-up is complete:

*Efficacy: The primary effectiveness end point will be improvement in pad weight defined as at least a 50% reduction in 24-hour pad weight from baseline to 12-months (including dry as defined as a pad weight of less than 1.3 grams during the 12-month test).
*Safety: Safety of the device, including the implant procedure, will be characterized by reporting adverse events including complications such as, but not limited to perforation, erosion, and hematoma, at 12 months.

Secondary outcome

Secondary objectives will assess subject satisfaction, patient reported pad use, and change in 24 hour pad weight through 36 months.

Secondary End Points:

The following secondary endpoints will be collected during the investigation. As labeling claims will not be made on these endpoints, formal statistical hypothesis tests are not specified and no adjustment of p-values for multiplicity is required. Subjects will be stratified into the three groups below by their 24 hour pad weight.

*24 Hour Pad Weight: 24 hour pad weight tests will be administered at baseline, 1, 3, 6, 12, 24 and 36 months and the difference reported. Outcomes reported will include mean paired change from baseline as well as the proportion or patients improving by at least 50% from baseline. For this purpose, results will be reported overall and by level of incontinence at baseline, divided into these specific categories:

*Group 1 (< 100 g)

*Group 2 (100 * 400 g)

*Group 3 (> 400 g)

*Pad Use: Number and types of pads used will be collected at baseline,1, 3, 6, 12, 24 and 36 months and the difference reported. For this purpose, results will be reported overall and by level of incontinence at baseline, divided into these specific categories:

According to the number of pad:

*Group A (0 or 1 dry pad for security / prophylactic reason)

*Group B (1 or 2 pads per day)

*Group C (3 or 4 pads per day)

*Group D (5 or more pads per day or condom catheter)

*ICIQ-UI: The ICIQ patient questionnaire will be administered at baseline, 1,

3, 6, 12, 24 and 36 months and the difference reported.

*PGI-I: The PGI-I patient questionnaire will be administered at 1, 3, 6, 12, 24 and 36 months and the patient reported improvement in urinary incontinence reported.

*USP questionnaire: The USP patient questionnaire will be administered at baseline, 1, 3, 6, 12, 24 and 36 months and help to score the stress urinary incontinence, bladder overactivity and dysuria

*Patient satisfaction score: The patient satisfaction will be evaluated at each visit after Virtue implantation.

Study description

Background summary

Estimates suggest that approximately 3.4 million men (17%) in the U.S. over the age of 60 have urinary incontinence (UI). Types of UI include urge incontinence, iatrogenic incontinence, spinal-cord-related incontinence, nocturnal enuresis, or other nonorganic causes. Although UI in men may occur for several reasons, reports suggest that up to 30% of subjects who have a radical prostatectomy have UI post-operatively to some extent.1 As the population ages, radical prostatectomy is becoming a common procedure for elderly males. There are approximately 74,200 radical prostatectomies performed each year in the US yielding about 25,000 men who would be candidates for some sort of incontinence treatment.2
The incidence of stress urinary incontinence (SUI) following radical prostatectomy surgery varies throughout the literature ranging from 8-77%.3 More conservative estimates suggest that up to 34% of men report persistent SUI following a radical prostatectomy.4 Inconsistencies in defining SUI contribute to the vast range of incidence. Such inconsistencies include distinguishing between *social* incontinence and SUI, and how to clinically diagnose SUI. Although there is variance in defining incontinence and determining treatment success, it is common across the literature that pad weight, pad use, quality of life and patient satisfaction all contribute to both defining incontinence and determining treatment success rates. Causes of male SUI can be due, but not limited to:
* Prostate problems

* Neurologic or degenerative conditions
* Infection
* Aging

Currently, treatment for UI includes behavioral therapies, pharmaceuticals, collagen implants, male slings, and artificial urinary sphincters (AUS). Although behavioral therapy, including pelvic floor muscle exercises, biofeedback, and bladder training, has been scientifically supported for the treatment of women with SUI, efficacy of this therapy in men is not yet ascertained. Treatment statistics using pharmaceuticals are positive for urge incontinence and overactive bladder; however, they are not efficacious for the treatment of SUI. When comparing slings to collagen injections, evidence suggests that slings provide longer-term efficacy where as collagen injections are more effective for short-term therapy.5 The AUS is considered the gold-standard with efficacy rates reported up to 75% for the post radical prostatectomy incontinence population, and patient satisfaction reported at 85-95%.6 Adverse event rates for the AUS range from six percent for mechanical failure and 27% for revisions.7 The invasive nature of the procedure and reported adverse events contribute to the AUS being used in more severely incontinent males. The male sling therapies are currently marketed to those subjects who are considered to be mild or moderately incontinent.8,9 However, it is documented that if given a choice without physician input, 92% of patients will choose to have a sling implanted rather than an AUS for the treatment of incontinence.10
Male slings currently available on the market have perceived drawbacks such as the presence of bone screws (which can lead to infection and pain), unclear methods for changing and maintaining sling tension (which can lead to migration and slippage), retropubic passage (which can lead to urethral or bladder perforations), and dissection through the bulbous urethra.11-13The design of Virtue® Male Sling is absent of bone screws and has four arms which may provide elongated compression of the bulbous urethra, without having to expose the urethra. The four arm design allows for compounded applied pressure to the bulbous urethra intra-operatively as evidenced in cadaveric tissue.14

Study objective

The Virtue male sling study in Europe is designed to assess efficacy and safety of the Virtue® Male Sling.

Study design

This study is a prospective, single arm, non-randomized, multi-center clinical study that will be conducted at up to thirteen centers in Europe. One hundred and twenty-one subjects, satisfying criteria for selection, will be implanted with no more than 15 implanted per site. The study*s primary end point will be evaluated at 12 months with continued data collection through 36 months.

Intervention

Surgical procedure: implantation of the Virtue male sling and creating tension to support the bulbous urethra with the aid of the two prepubic arms and 2 transobturator arms of the sling. The surgical procedure takes place under general aneasthesia or spinal anaesthesia.

Study burden and risks

Burden:
1. Pre-surgery visit and examination (does not differ from standard examination for implants) and baseline examination

The Baseline Visit will occur once the decision has been taken to include the patient in the Virtue study and after informed concent of the patient. This visit will occur prior to implantation of the Virtue. The medical history that relates to the urinary incontinence will be recorded. The patient is asked to fill out 3 validated questionnaires (20 questions) about urine leakage, pad use, and how urine leakage affects the daily life activities. Also, some tests will be done to determine theseverity of incontinence and to ensure that the patient has not a urinary tract infection. These tests are described below:
*Urodynamics
*Post Void Residual
*Uroflow Testing
*Urethro Cystoscopy
*24-hour pad weight; the patient performs this test 24 hours before the next visit to the doctor
*Urinalysis

2. Implant Visit
The patient will be administered to the hospital 24 to 36 hours and the VirTue male sling will be implanted while trhe patient is fully anesthetized.

3. Follow-up Visits
The patient has to visit the hospital 1, 3, 6, 12, 24 and 36 months after implantation of the male sling. During thes follow up visits the patient has to to complete three (20 questions) questionnaires. Some of the same tests that were completed prior to the surgery will be completed at each follow-up visit. These tests will be completed to see if any change has occurred in relation to the patients incontinence.
The following tests will be completed at every follow-up visit:
*Post Void Residual
*Uroflow Testing
*24-hour pad weight: the patient performs this test 24 hours before the next visit to the doctor

Potential risks (do not differ from other surgeries in the pelvic floor):
Procedure Related
*Delayed wound healing
*Bleeding/Hematoma
*Possible reaction from anesthesia
*Parasthesia (genital)
*Perineal pain
*Suprapubic pain
*Superficial wound infection
*Infection at implant site
*Bladder perforations
*Urethral perforations
*Vascular injury
*Nerve injury
*Urinary tract infection (with or without fever)

Device Related risks
*Erosion - sling enters the bladder or urethral lumen
*Urinary retention requiring a catheterization
*Foreign body reaction
*Device malfunction * sling does not improve subject*s stress urinary incontinence and only if it causes patients symptoms beyond what they had.

Contacts

Public
Coloplast BV

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

*the subject is male
*the suject is at least 18 years of age
*the subject has an estimated life expectancy of more than 5 years
*the subject has confirmed stress urinary incontinence (SUI) throug medical history, urodynamics and/or pysical exam for at least 6 months
* the subject has intrinsic sphincter deficiency due to radical prostatectomy completed at least 1 year prior to implantation date
*the subject has a good bladder function
*the subject has failed non-invasive therapies eg. Pelvic Floor/Kegel exercises, behavioral modification or biofeedback for at least 6 months
*the subject is willing to have the Virtue male sling implanted
*the subject is able and willing to complete all follow-up visits and procedures indicated in this protocol.

Exclusion criteria

*the subject is unable or unwilling to comply with all follow-up requirements according to the study protocol
*the subject has an active urinary tract infection or active skin infection in region of surgery
*the subject has compromised immune systems or any other conditions affect healing
*the subject has serious bleeding disorders
*the subject has an urinary incontinence that is not mainly a stress urinary incontinence
* the subject has a stress urinary incontinence due to TransUrethralResection or laser surgery of the prostate (TURP)
*the subject has incontinence due to neurogenic causes defined as multiple sclerosis, spinal cord/brain injury, CVA, detrusor-external sphincter dyssynergia, Parkinson's disease or similar conditions.
*the subject had a previous implant (male sling, Artificial Urinary Sphincter) to treat stress urinary incontinence (previous implanted bulking agensts are allowed)
*the subject has undergone radiation, cryosurgery or brachy therapy to treat prostate- or pelvic cancer within 6 months.

*the subject is likely to undergo radiation therapy within the next 3 months
*the subject has a postvoid residual (PVR) equal to or more than 150 ml
*the subject has recently required transurethral instrumentation for urethral or urethro-vesical anatomosis stricture within the previous 6 months.
* the subject is enrolled in a concurrent clinical study of any treatment (drug or devise) that could affect continence function without the sponsors'approval.
* the subject is deemed unfit for male sling implantation or participation in a research protocol as determined by the attending physician

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-10-2012
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	Virtue male sling
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	08-06-2012
Application type:	First submission

Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	22-04-2014
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL39560.058.12