A Prospective, Multi-centre Study to Evaluate the Clinical Performance of TVTO-PA as Treatment for Stress Urinary Incontinence

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON36399

Source
ToetsingOnline

Brief title
TVTO_PA

Condition

- Other condition

Synonym
Stress Urinary Incontinence

Health condition

Stress Urinary Incontinence

Research involving

Human

Sponsors and support

Primary sponsor: Johnson & Johnson
Source(s) of monetary or material Support: Ethicon Clinical Development & Medical Affairs (CDMA);Johnson & Johnson Medical Ltd;UK

Intervention

Keyword: Stress Urinary Incontinence, TVT-O (Tension free Vaginal Tape (Obturator route)), TVTO-PA (Tension free Vaginal Tape (Obturator route) Partially Absorbable)

Outcome measures

Primary outcome

The primary outcome will be the objective cure of urinary incontinence at 12

months after surgery.

Objective Success will be defined as:

* A negative SCST without surgical re-intervention for SUI

Patients who are considered to fail based on the above criteria will be asked

to approximate the date of recurrent symptoms in order that a Kaplan-Meier

survival curve of time to failure is developed. Surgical re-intervention will

include surgical repair of SUI, which will include placement of a further

mid-urtheral sling and / or administration of bulking agents.

Secondary outcome

Subjective Success defined by:

* A response of "Very much better" or "Much better" in PGI-I at 12 months

Symptom Change defined as:

* Change from baseline in incontinence-specific symptoms assessed by UDI-6 at

12 months

* Change from baseline in incontinence-specific quality of life assessed by

IIQ-7 at 12 months

* Change from baseline in ICIQ- SF at 12 months

Study description

Background summary

Stress urinary incontinence (SUI) is estimated to affect up to a third of adult women, and the number of women receiving surgical intervention continues to increase. Although both Tension free Vaginal Tape (TVT) and Tension free Vaginal Tape (Obturator route) (TVT-O) have high objective cure rates for SUI, and are associated with low complication rates, mesh related complications such as mesh exposure, and mesh retraction continue to occur. In an effort to minimize the amount of mesh placed within the patient in the long-term, a partially absorbable version of TVT-O (TVTO-PA: Tension free Vaginal Tape (Obturator route) Partially Absorbable) has been developed.The purpose of this clinical study is to evaluate the clinical performance of TVTO-PA. The study will also assess TVT-O PA for non inferiority to TVT-O.

Study objective

The primary objective of this study is to determine if TVTO-PA is non-inferior to TVT-O in the objective cure of women with Stress Urinary Incontinence (SUI). The secondary objectives of the study are to evaluate changes in incontinence-specific symptoms and quality of life following surgery for SUI using TVTO-PA. Safety will be evaluated.

Study design

This will be a prospective, multi-centre, single-arm study design. The study will be split into two groups, which will be enrolled sequentially at site level:
1) Device Run-In (DRI) Group: to ensure that each investigator adopts the optimal tensioning technique for TVTO-PA;
2) Outcomes Group: to determine the effectiveness of TVTO-PA.

Device Run-In (DRI) Group

Each investigator will be required to complete a minimum of three DRI patients. Following surgery, each DRI will have a Standardized Cough Stress Test (SCST) at 1 week (+/- 1day) post procedure to ensure that any learning from the tensioning of TVTO-PA is obtained prior to performing surgery on the next DRI case. Each investigator will need to complete 3 DRIs with negative SCST results prior to enrolling into the Outcomes group. There will be an upper limit of six on the overall number of DRIs each investigator is allowed to complete; in the event that an investigator does not achieve the DRI criteria to move to the Outcomes group, the site will be closed to further enrolment.
The DRI patients will be considered study subjects, and written informed consent obtained prior to participation in the study. Subjects will be assessed prior to surgery, during and after the procedure, at 1 week, 6 weeks and 6 months post-procedure. Every DRI patient will be followed up to 6 months for evaluation of safety and effectiveness. The DRI data will be analyzed completely separately from the main outcomes study.
At any stage during the DRI group of this study, if deemed appropriate either by the investigator and/or Ethicon Women*s Health and Urology (EHWU) Medical Affairs, a Clinical Observer (CO) from Medical Affairs will attend TVTO-PA procedures. Any key learning experiences observed during the DRI group will be disseminated to the investigator team.

Outcomes Group
Once each Investigator has successfully completed the DRI group of the study, they may start enrolment into the Outcomes Group. Enrolment will be competitive, but each site will be limited to a maximum of 25 patients.
Subjects must give written informed consent prior to any study related procedures. Subjects will be assessed prior to surgery, during and after the procedure, at 6 weeks and 6, 12, 24 and 36 months post-procedure.
At baseline, if the patient has already undergone any of the following investigations within 3 months prior to the study start, and the investigator considers it is inappropriate to repeat the investigation, the retrospective data may be used. The use of these retrospective data will also apply to the DRI subjects (Patient approval for retrospective data use is requested in the study patient information leaflet and consent):
* POP-Q assessment, performed in accordance with the International Continence Society method of quantifying pelvic organ prolapse.
* Cough stress test (CST).
Objective success will be measured using a SCST. Patient reported outcomes will be evaluated using the following questionnaires, which will be completed by the patients in their local language:
* Urinary Distress Inventory-6 (UDI-6)
* Incontinence Impact Questionnaire-7 (IIQ-7)
* International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-SF)
* Patient Global Impression of Improvement (PGI-I)
* Pelvic Organ Prolapse / Urinary Incontinence Sexual Questionnaire-12

(PISQ-12); for sexually active patients only

Intervention

All patients who meet the inclusion/exclusion criteria in both the device run in and outcomes group will undergo surgical intervention with TVTO-PA.

Study burden and risks

It can be anticipated that TVTO-PA will have similar risks to the TVT-O device. Listed below are the complications that have occurred in previous TVT-O studies and in general use.

Device Adverse Events

* Urinary tract infection
* Urinary frequency or urgency
* Difficulty in passing urine or being unable to pass urine
* Inability to fully empty your bladder
* Thigh/groin pain
* Discomfort/Pain during sex
* Mesh erosion into the vagina
* Mesh erosion into the urethra or bladder
* Wound infection
* Bleeding
* Bladder injury
* Urethral injury
* Fistula formation
* Unintended tissue reaction
* Persistent symptoms of stress urinary incontinence

Potential Procedural Adverse Events
Potential adverse events associated with urogynecological procedures include, but are not limited to the following:

* Anesthesia reaction (e.g. spinal headache)
* Deep vein thrombosis
* Hematoma
* Life-threatening cardiac or respiratory arrest or other life-threatening event
* Pulmonary embolism possibly leading to death (clot in the lung)
* Upper urinary tract infection
* Adverse events associated with anesthesia

Anticipated Post-Procedural Complications
For any urogynecologic procedure, with or without anesthesia, commonly reported post-procedure events include the following:

* Fatigue
* Headache
* Nausea and vomiting
* Bleeding
* Febrile morbidity

In some cases these events can be life-threatening. There may be risks associated with the study device that are currently unknown.

There is a possibility that the Stress Incontinance will not cure and the patient might experience some or more of the previously mentioned side effects.

The procedure could cure or improve the symptoms of Stress Incontinance significantly. Cure rates are high with vaginal tape procedures however; there is no guarantee of a cure. The stress urinary incontinence symptoms may improve, stay the same, or worsen.

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

1. Subjects with demonstrable SUI diagnosed by CST, suitable for surgical repair.
2. Age ><=18 years.
3. Agrees to participate in the study, including completion of all study-related procedures, evaluations and questionnaires, and documents this agreement by signing the Ethics Committee approved informed consent.
4. Post-void residual volume <100ml as determined prior to the SCST

Exclusion criteria

1. Previous surgical treatment for SUI.
2. Requirement for any concurrent gynecological procedures.
3. Associated pelvic organ prolapse (either symptomatic and/or leading edge >0cm)
4. Exhibits a clinical history of predominantly OAB symptoms.
5. Current anti-cholinergic use.
6. Experimental drug or experimental medical device within 3 months prior to the planned procedure.
7. Active genital, urinary or systemic infection at the time of the surgical procedure. Surgery may be delayed in such subjects until the infection is cleared.
8. Coagulation disorder or on therapeutic anticoagulant therapy at the time of surgery.
9. History of pelvic radiation.
10. Systemic disease known to affect bladder or bowel function (e.g. Parkinson*s disease, multiple sclerosis, spina bifida, spinal cord injury or trauma).
11. Nursing, pregnant or intends future pregnancy.
12. In the investigator*s opinion, any medical condition or psychiatric illness that could potentially be life threatening or affect their ability to complete the study visits according to this protocol.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2011
Enrollment:	100
Type:	Anticipated

Medical products/devices used

Generic name:	GYNECARE TVTO -PA Obturator Continence System
Registration:	No

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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
Other	Clinicaltrials.gov number pending
CCMO	NL34848.018.10