INJECTABLE BULKING AGENT FOR MALE URINARY INCONTINENCE TREATMENT: A MULTI-CENTRE EFFECTIVENESS AND SAFETY PILOT STUDY

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Urethral disorders (excl calculi)
Study type	Interventional

Summary

ID

NL-OMON43352

Source
ToetsingOnline

Brief title
Opsys bulking agent for male incontinence

Condition

- Urethral disorders (excl calculi)

Synonym
incontinence, urine loss

Research involving
Human

Sponsors and support

Primary sponsor: Ziekenhuisgroep Twente

Source(s) of monetary or material Support: geen financiering extern nodig

Intervention

Keyword: bulking agent, opsys, post radical prostatectomy incontinence

Outcome measures

Primary outcome

Primary endpoint:

* Two 24 h Pad Weight Test (PWT)

Secondary outcome

Secondairy endpoints:

* 48 h voiding diary to record micturition episodes

* Complete Urinalysis with Urine culture

* Urodynamic evaluation:

o Uroflowmetry

o Urethral pressure (leak point pressure measurement before and after

surgery)

o Cystometric test

o Post Void Residual Measurement

* International Consultation on Incontinence Questionnaire * Short Form

(ICIQ-UI-SF)

* Incontinence Impact Questionnaire * Short Form (IIQ-7)

* Patient Global Impression of Improvement (PGI-I)

* Urogenital Distress Inventory * Short Form (UDI-6)

Study description

Background summary

The investigational device Opsys is a permanent-action and definitive tissue bulking non-absorbable substance suitable to treat male and female Stress Urinary Incontinence (SUI). It consists of particles of polyacrylate polyalcohol copolymer (PPC) immersed in a glycerol and physiological solution carrier. It has a very high molecular mass and it comes in the form of sterile pyrogen-free particles that are flexible and highly deformable by compression. When injected in soft tissue, the carrier is eliminated by the reticuloendothelial system without metabolizing and excreted through the kidneys. The macroparticles stay, enlarging the volume of the tissue generating a minimum fibrotic growth around them, producing tissue bulkiness that remains stable throughout time. Opsys produces urethral coaptation, given the bulkiness effect on the urethral submucosa, restoring urinary continence. This bulking agent is to be used only in accordance with this approved Clinical Investigational Plan on subjects who have signed an informed consent form. Device use is limited to the approved study investigators.

Study objective

Hypothesis: Opsys will improve mild incontinence based on urine loss per 24 h measured by 24 h pad test.
The main objective of this study is to test the effectiveness of Opsys in a group of selected subjects with minimal to mild (less than 30 g per day urine loss on 24 h pad weight test) post-radical prostatectomy SUI.
The secondary goals that this study pursues are:
* Quality of life assessment regarding their post-implantation condition.
* Usage of fewer pads per day.
* Frequency of expected adverse events.
* To assess the surgical technique regarding the optimal volume injected and injection sites.
* To evaluate safety endpoints.

Study design

This is a post market, prospective, open label, and non-comparative pilot study involving male adult subjects. This is an unmasked study where subjects and surgeons are not blind to the procedure.

Intervention

Opsys will be implanted using a video endoscope with a transurethral injection

needle.

Study burden and risks

Anticipated clinical benefits
In SUI - ISD treatment, Opsys is transurethrally implanted around the sphincter area of the urethra to achieve the coaptation of the urethra during storage phase and maintenance of that coaptation during periods of increased abdominal pressure. Consequently, anticipated clinical benefits expected with the use of Opsys are to achieve subject continence.

Anticipated adverse device effects - possible complications
Opsys components have been designed to be used only once. Therefore, it cannot be reuse or resterilize, as this can potentially result in compromised device performance and increased risk of inappropriate resterilization and cross contamination.
The possible complications regarding the use of Opsys must be discussed with the subject prior to surgery. Complications regarding the implantation of an injectable agent include those common to these types of procedures:
* Dysuria
* Urinary infection
* Haematuria
* Voiding pain and pain in injection site
* Acute urinary retention
* Long-term adverse effects with low probability of occurrence: urinary retention, abscess formation, fibrosis, migration and necrosis.
Excessive repair could lead to urinary retention or inability to urinate. If urinary retention occurs within the immediate period following implant surgery, a catheterization should be performed using a 12-Fr catheter, or preferably smaller, until normal urination is restored. Usual precautions regarding catheter handling and insertion must be taken in order to prevent infection.
As with all implants, existing infection could be exacerbated by Opsys.

It is important to remark that there is not any additional risk or benefit for subjects who will participate in this study in terms of neither the investigational device nor the clinical investigation per se in comparison to those regular patients who will undergo a surgery with Opsys (i.e. out of the study).
There is no difference between the bulking agent which will be used in this study and the bulking agent (both named Opsys) available in the market. Regular Opsys will be delivered to investigational centres to be used as investigational devices. In other words, the investigational devices will be manufactured by the same materials and processes as the ones approved for commercialization, so they will share the same characteristics and properties.
The lack of any differences between investigational devices and those commercially available justify the absence of any additional risk, in terms of

the device

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

Inclusion criteria:
* Male, aged between 18 and 85 years old.
* Subject remains dry at night.
* Ability to voluntarily stop micturition.
* Stress Urinary Incontinence caused by Intrinsic sphincter deficiency ISD secondary to a post RP, refractory to conservative treatment with a post-operative of at least 12 months.
* Urinary incontinence classified as minimal to mild incontinence level by a 24 h pad weight test mentioned in the clinical data (less than 30 g per day urine loss on 24 h pad weight test), and quality of life has deteriorated so as to require surgery as a method of treatment.

* Consent informed signed.

Exclusion criteria

Exclusion criteria:
* Post-prostatectomy radiotherapy or brachytherapy.
* Subject radiated as treatment of Prostate Cancer, being this interstitial or external, neo-adjuvant, therapeutic or adjuvant.
* Bladder neck sclerosis or urethral stricture.
* Detrusor hyperactivity.
* Lower Urinary Tract Infections
* Urge Incontinence.

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):	15-08-2016
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	Opsys bulking agent
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	16-06-2016
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	16-08-2016
Application type:	Amendment
Review commission:	METC Twente (Enschede)

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	NL57054.044.16