Opsys bulking agent bij mannelijke incontinentie

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26801

Source
NTR

Brief title
OPSYS

Health condition

mannelijk incontinentie
bulking stof

male incontinence
bulking agent

Sponsors and support

Primary sponsor: Not sponsored trial

performer ZGT and Jeroen Bosch Ziekenhuis

Source(s) of monetary or material Support: no funding

self financing research: fund = initiator=

Intervention

Outcome measures

Primary outcome

The main study endpoint is whether treatment was successful, based on the two 24 h pad weight test (PWT) before and after treatment. The success rate of the procedure will be assessed according to the following criteria presented in Table 2.

Table 2. Criteria for defining treatment success, improvement and failure.

Result Criteria

Endpoint Actual value Endpoint Actual value
SUCCESS 24-h PWT 0 -3 g OR Voiding diary
(Count pads) 0 pads

IMPROVEMENT 24-h PWT ¡Ý 50% reduction OR Voiding diary

(Count pads) ¡Ý 50% less usage of pads

FAILURE Unable to meet the previous criteria

Secondary outcome

Secondary endpoints are:

• 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 ¨C Short Form (ICIQ-UI-SF)

• Incontinence Impact Questionnaire ¨C Short Form (IIQ-7)

• Patient Global Impression of Improvement (PGI-I)

• Urogenital Distress Inventory (UDI-6)

Safety endpoints are:

• Record of intraoperative complications (including device and surgical instrument (needle) complications and procedure related problems).

• Record of postoperative complications (e.g. urinary retention, voiding pain, etc.).

• Visual Analogue Scale for assessment of pain (pre- and postoperative).

• Any other adverse events regarding safety issues will be recorded and followed-up after their appearance.

Study description

Study objective

The primary hypothesis of this study is that Opsys will improve mild incontinence based on urine loss per 24 h measured by 24 h pad weight test (PWT).

Primary Objective

The primary objective of this study is to test the effectiveness of Opsys in a controlled group of selected subjects with mild (less than 30 g per day urine loss on 24 h pad weight test) post-radical prostatectomy SUI, based on urine loss per 24 h measured by 24 h pad weight test.

Study design

All visits

Pre-operative

(1 mo)

(3 mo)

(6 mo)

(12 mo)

(24 mo)

(36 mo)

(60 mo)

Intervention

Opsys will be implanted in urethra using a video endoscope with a transurethral injection needle. All the procedures will be recorded on CD-Rom.

Contacts

Public
Ziekenhuis groep Twente

E.B. Cornel
postbus 546

Hengelo 7550 AM
The Netherlands
Scientific
Ziekenhuis groep Twente

E.B. Cornel
postbus 546

Hengelo 7550 AM
The Netherlands

Eligibility criteria

Inclusion criteria

• 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 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.

Subjects will be physical and urodynamically examined to confirm RP SUI. The degree of urine leakage will be quantified using two 24 h pad weight test

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.

• Urge Incontinence

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-06-2016
Enrollment:	0

Type:	Anticipated

Ethics review

Positive opinion Date:	25-07-2016
Application type:	First submission

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
NTR-new	NL5846
NTR-old	NTR6001
Other	: abr NL5705404416

Study results