Opsys bulking agent bij mannelijke incontinentie

Gepubliceerd: 25-07-2016 Laatst bijgewerkt: 18-08-2022

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...

Ethische beoordeling	Positief advies
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26801

Bron
Nationaal Trial Register

Verkorte titel
OPSYS

Aandoening

mannelijk incontinentie
bulking stof

male incontinence
bulking agent

Ondersteuning

Primaire sponsor: Not sponsored trial

performer ZGT and Jeroen Bosch Ziekenhuis

Overige ondersteuning: no funding

self financing research: fund = initiator=

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Doel van het onderzoek

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.

Onderzoeksopzet

All visits

Pre-operative

(1 mo)

(3 mo)

(6 mo)

(12 mo)

(24 mo)

(36 mo)

(60 mo)

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders

Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-06-2016
Aantal proefpersonen:	0
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	25-07-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5846
NTR-old	NTR6001
Ander register	: abr NL5705404416

Resultaten