The use of a bulking agent (UrolonTM) for the treatment of Female Stress Urinary Incontinence.

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This is a prospective pivotal trial to study the safety and efficacy of a PCL-based bulking agent (UrolonTM) for stress urinary incontinence

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

Samenvatting

ID

NL-OMON28659

Bron
NTR

Verkorte titel
Stress Urinary Incontinence

Aandoening

Stress Urinary Incontinence (SUI)
Female Subjects
18 years of age or older

Ondersteuning

Primaire sponsor: AQLANE Medical BV.
Yalelaan 1, 3584 CL Utrecht
The Netherlands
Overige ondersteuning: AQLANE Medical BV.
Yalelaan 1, 3584 CL Utrecht
The Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. The primary objective of this trial is to assess the treatment efficacy of the PCL-based bulking agent (UrolonTM-12, UrolonTM-24 and UrolonTM-48) as determined by the SGS. The efficacy endpoint is a reduction of at least 1 SGS at 3, 6, 12, 18, and 24 months follow-up compared to baseline.
2. The primary objective of this trial is to evaluate the safety of the PCL-based bulking agent (UrolonTM-12, UrolonTM-24 and UrolonTM-48). Counts and rates of treatment-related AE's and SAE's will be presented immediately after treatment (baseline) and at the 3, 6, 12, 18 and 24 follow-up time points.

Toelichting onderzoek

Achtergrond van het onderzoek

Objectives

The primary objectives of the trial are to:

 Evaluate the efficacy of the PCL-based bulking agent treatment as determined by the Stamey Grading System (SGS). The SGS will be determined at baseline, 3, 6, 12, 18, and 24 months follow-up.

 Evaluate the safety of the PCL-based bulking agent treatment via any reported adverse events at baseline, 3, 6, 12, 18, and 24 months follow-up.

The secondary objectives of the trial are to:

 Evaluate the effect on Quality of Life (QoL) after the PCL-based bulking agent treatment. QoL will be determined with the use of Incontinence Quality of Life questionnaire (I-QoL). The I-QoL will be determined at baseline and at 3, 6, 12, 18, and 24 months follow-up.

 Evaluate the efficacy after the PCL-based bulking agent treatment. Efficacy will be

determined with the use of the International Consultation on Incontinence Questionnaire - Short Form (ICIQ-SF). The ICIQ-SF will be determined at baseline and at 3, 6, 12, 18, and 24 months follow-up.

 Evaluate the efficacy after the PCL-based bulking agent treatment. Efficacy will be determined with the use of the Patient's Global Impression of Improvement scale (PGI-I) and Patient's Global Impression of Severity scale (PGI-S). The PGI-I will be determined at 3, 6, 12, 18, and 24 months follow-up. The PGI-S will be determined at baseline, 3, 6, 12, 18, and 24 months follow-up.

 Evaluate efficacy as determined by the non-invasive cough test. The non-invasive cough test will be performed at baseline, after treatment, and at 3, 6, 12, and 24 months follow-up.

 Evaluate safety via an additional cystoscopic examination at 12 and 24 months follow-up.

 Long-term safety and efficacy will be assessed by extending the follow-up visits annually up to 5 years (SGS, I-QoL, PGI-I, PGI-S, and ICIQ-SF).

Trial Design

This is a prospective pivotal trial to study the safety and efficacy of a PCL-based bulking agent (UrolonTM) for stress urinary incontinence (SUI)

Trial Population

Female subjects with stress urinary incontinence (SUI)

Number of Subjects:

A total of 50 subjects will be treated with the PCL-based bulking agent (UrolonTM) at three separate investigation sites. More specifically, 10 subjects will receive UrolonTM-12, 30 subjects will receive UrolonTM-24, and 10 subjects will receive UrolonTM48.

Trial Duration

The duration of the trial will be 24 months with a view to extending up to 5 years

Inclusion Criteria

1. Subjects 18 years of age or older

2. Subjects with predominant SUI as determined by the Questionnaire for Urinary Incontinence Diagnosis (QUID); Total Stress Score (Sum Q1-Q3) of > or equal to 4 and Total Urge Score (Sum Q1-Q6) of < 6.

3. Subjects with mild to moderate SUI as confirmed by SGS 1 or 2.

4. Subjects who attempted or failed prior noninvasive pelvic muscle rehabilitation treatment while incontinent.

5. Subjects willing and able to comply with study follow-up procedures and schedule.

6. Subjects willing to provide written informed consent for their participation in the trial.

Exclusion Criteria

1. Subjects who have received previous bulking agent implantation in the submucosa of the urethra or had any form of surgery to treat SUI.

2. Subjects with any form of urinary incontinence other than predominant SUI.

3. Subjects with urinary retention (post void residual volume > or equal to 100mL)

4. Subjects with morbid obesity (body mass index BMI > or equal to 40 kg/m^2)

5. Subjects with known allergies to antibiotics.

6. Subjects with a neurogenic bladder.

7. Subjects who were treated with chemotherapy agents or systemic corticosteroids within 3 months prior to enrollment.

8. Subjects with a history of autoimmune disorder.

9. Subjects with known allergies to topical, injectable, or general anesthetics.

10. Subjects with severe allergies manifested by a history of anaphylaxis or those with severe, chronic allergies (e.g. asthma).

11. Subjects with a known bleeding disorder.

12. Subjects with an active infection of any kind at the time of enrollment.

13. Subjects with known connective tissue disease.

14. Subjects who do not agree to use contraceptives throughout the initial 12 months of the trial.

15. Subjects who are pregnant (or within 12 months postpartum) or lactating.

16. Subjects who are unwilling and/or unable to comply trial follow-up procedures and schedules.

17. Subjects enrolled in another investigational clinical trial.

18. Subjects with co-morbidities

19. Subjects with non-viable tissue, e.g. history of significant pelvic irradiation, multiple pelvic surgeries, etc. (scar tissue and significantly compromised tissue will not coapt approprately).

20. Subjects with urethral or bladder neck strictures (use of bulking agents in patients with strictures may cause injury and/or urethral obstruction).

21. Subjects with peripheral vascular disease and/pr pelvic surgery may be at increased risk for tissue erosion.

Investigational Product

The PCL-based bulking agent is a sterile, non-pyrogenic, bioresorbable implantable device, whose principle component is synthetic polycaprolactone microspheres suspended in a gel carrier of sterile phosphate buffered saline, glycerin and sodium carboxymethylcellulose (CMC).

Trial Procedures

Eligible subjects will receive injections of the PCL-based bulking agent (UrolonTM-12, UrolonTM-24, or UrolonTM-48). The use of topical, spinal, or general anesthesia is permitted at the discretion of the Investigator. The PCL-based bulking agent injection will be administered into the submucosa of the urethra at the bladder neck using the

transurethral technique with a 21 gauge needle. Three injections (2, 6, and 10 o'clock positions) will be administered in order to achieve optimal coaptation of the urethral mucosa. A second injection only with the corresponding PCL-based bulking agent (UrolonTM-12, UrolonTM-24, or UrolonTM-48) used for initial treatment is permitted if the patient was not dry after the first treatment. If required, a second injection is permitted at 3 month follow-up and or trial exit.

Schedule of Visits

At baseline, 3, 6, 12, 18, and 24 months post treatment the treated subjects have an assessment of safety and efficacy as determined by subjective and objective methods. Long-term safety and efficacy will be assessed by extending the follow-up visits annually up to 5 years (SGS, I-QoL, PGI-I, PGI-S, and ICIQ-SF).

Trial Endpoints

1. Primary analyses

 Primary efficacy analysis

The primary objective of this trial is to assess the treatment efficacy of the PCL-based bulking agents UrolonTM-12, UrolonTM-24, and UrolonTM48 as determined by the SGS. The efficacy endpoint is a reduction of at least 1 SGS at 3, 6, 12, 18, and 24 months follow-up compared to baseline.

 Primary safety analysis

The primary objective of this trial is to evaluate the safety of the PCL-based bulking agents UrolonTM-12, UrolonTM-24, and UrolonTM48. Counts and rates of treatment-related AE's and serious AE's will be presented immediately after treatment (baseline) and at the 3, 6, 12, 18, and 24 month follow-up time points.

2. Secondary analyses

 Secondary efficacy analysis

The secondary objective of this trial is to assess the efficacy and improvement in patients QoL after treatment with the PCL-based bulking agents UrolonTM-12, UrolonTM-24, and UrolonTM48 as determined with the I-QoL, ICIQ-SF, PGI-I, PGI-S, and non-invasive cough-test.

The efficacy and QoL endpoints are improvement at 3, 6, 12, 18 (no cough-test at this time-point), and 24 months follow-up compared to baseline with the use of the I-QoL, ICIQ-SF, PGI-I, PGI-S, and non- invasive cough-test. The non- invasive cough-test will be performed after treatment to test post-treatment success.

 Secondary efficacy and safety analysis

The secondary objective of this trial is to assess the long-term safety and efficacy which will be assessed by extending the follow-up visits annually up to 5 years. (SGS, I-QoL, PGI-I, PGI-S, and ICIQ-SF). Evaluate safety via an additional cystoscopic examination at 12 and 24 months follow-up

Doel van het onderzoek

This is a prospective pivotal trial to study the safety and efficacy of a PCL-based bulking agent (UrolonTM) for stress urinary incontinence

Onderzoeksopzet

The duration of the trial will be 24 months with a view to extending up to 5 years.

At baseline, 3, 6, 12, 18 and 24 months post treatment the treated subjects have an assessment of safety and efficacy as determined by subjective and objective methods. Long-term safety and efficacy will be assessed by extending the follow-up visits annually up to 5 years (SGS, I-QoL, PGI-I, PGI-S and ICIQ-SF).

Onderzoeksproduct en/of interventie

Eligible subjects will receive injections of the PCL-based bulking agent (UrolonTM-12; UrolonTM-24; or UrolonTM-48). The use of topical and/or local anesthesia is permitted at the discretion of the investigator. The PCL-based bulking agent injection will be administrated into the submucosa of the urethra at the bladder neck using the transurethral technique with a 21 guage needle. Three injections (2, 6, and 10 o'clock positions) will be administrated in

order to achieve optimal coaptation of the urethral mucosa. A second injections only with the corresponding bulking agent is permitted if the patient was not dry after the first treatment. If required, a second injection is permitted at 3 months follow-up and or trial exit.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Subjects 18 years of age or older

2. Subjects with predominant SUI as determined by the Questionnaire for Urinary Incontinence Diagnosis (QUID); Total Stress Score (Sum Q1-Q3) of > or equal to 4 and Total Urge Score (Sum Q1-Q6) of < 6.

3. Subjects with mild to moderate SUI as confirmed by SGS 1 or 2.

4. Subjects who attempted or failed prior noninvasive pelvic muscle rehabilitation treatment while incontinent.

5. Subjects willing and able to comply with study follow-up procedures and schedule.

6. Subjects willing to provide written informed consent for their participation in the trial.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Subjects who have received previous bulking agent implantation in the submucosa of the urethra or had any form of surgery to treat SUI.

2. Subjects with any form of urinary incontinence other than predominant SUI.

3. Subjects with urinary retention (post void residual volume > or equal to 100mL)

4. Subjects with morbid obesity (body mass index BMI > or equal to 40 kg/m^2)

5. Subjects with known allergies to antibiotics.

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7. Subjects who were treated with chemotherapy agents or systemic corticosteroids within 3 months prior to enrollment.

8. Subjects with a history of autoimmune disorder.

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10. Subjects with severe allergies manifested by a history of anaphylaxis or those with severe, chronic allergies (e.g. asthma).

11. Subjects with a known bleeding disorder.

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15. Subjects who are pregnant (or within 12 months postpartum) or lactating.

16. Subjects who are unwilling and/or unable to comply trial follow-up procedures and

schedules.

17. Subjects enrolled in another investigational clinical trial.

18. Subjects with co-morbidities

19. Subjects with non-viable tissue, e.g. history of significant pelvic irradiation, multiple pelvic surgeries, etc. (scar tissue and significantly compromised tissue will not coapt approprately).

20. Subjects with urethral or bladder neck strictures (use of bulking agents in patients with strictures may cause injury and/or urethral obstruction).

21. Subjects with peripheral vascular disease and/pr pelvic surgery may be at increased risk for tissue erosion.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2016
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	27-07-2016
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	NL5760
NTR-old	NTR6002
Ander register	NL55843.100.15 ; AFMPS/80M0633 : 1001-019

Resultaten

Samenvatting resultaten
Not applicable