

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

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON28659

### Source

Nationaal Trial Register

### Brief title

Stress Urinary Incontinence

### Health condition

Stress Urinary Incontinence (SUI)

Female Subjects

18 years of age or older

## Sponsors and support

**Primary sponsor:** AQLANE Medical BV.

Yalelaan 1, 3584 CL Utrecht

The Netherlands

**Source(s) of monetary or material Support:** AQLANE Medical BV.

Yalelaan 1, 3584 CL Utrecht

The Netherlands

## Intervention

## Outcome measures

### Primary outcome

1. The primary objective of this trial is to assess the treatment efficacy of the PCL-based bulking agent (Urolon™-12, Urolon™-24 and Urolon™-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 (Urolon™-12, Urolon™-24 and Urolon™-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.

### Secondary outcome

1. The secondary objective of this trial is to assess the efficacy and improvement in patients QoL after treatment with the PCL-based bulking agents (Urolon™-12, Urolon™-24 and Urolon™-48) 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.
2. 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.

## Study description

### Background summary

#### 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 (Urolon™) 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 (Urolon™) at three separate investigation sites. More specifically, 10 subjects will receive Urolon™-12, 30 subjects will receive Urolon™-24, and 10 subjects will receive Urolon™48.

## 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  $\geq 4$  and Total Urge Score (Sum Q4-Q6) of  $\leq 6$ .
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  $\geq 100$  mL)

4. Subjects with morbid obesity (body mass index BMI  $\geq$  40 kg/m<sup>2</sup>)
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 appropriately).
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/or 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 (Urolon<sup>TM</sup>-12, Urolon<sup>TM</sup>-24, or Urolon<sup>TM</sup>-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 (Urolon<sup>TM</sup>-12, Urolon<sup>TM</sup>-24, or Urolon<sup>TM</sup>-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 Urolon<sup>TM</sup>-12, Urolon<sup>TM</sup>-24, and Urolon<sup>TM</sup>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.

#### □ Primary safety analysis

The primary objective of this trial is to evaluate the safety of the PCL-based bulking agents Urolon™-12, Urolon™-24, and Urolon™48. 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 Urolon™-12, Urolon™-24, and Urolon™48 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

## **Study objective**

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

## **Study design**

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).

## **Intervention**

Eligible subjects will receive injections of the PCL-based bulking agent (Urolon<sup>TM</sup>-12; Urolon<sup>TM</sup>-24; or Urolon<sup>TM</sup>-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 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 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.

## **Contacts**

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## **Eligibility criteria**



## **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  $\geq 4$  and Total Urge Score (Sum Q1-Q6) of  $< 6$ .
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4. Subjects who attempted or failed prior noninvasive pelvic muscle rehabilitation treatment while incontinent.
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## **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  $\geq 100\text{mL}$ )
4. Subjects with morbid obesity (body mass index BMI  $\geq 40 \text{ kg/m}^2$ )
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12. Subjects with an active infection of any kind at the time of enrollment.
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21. Subjects with peripheral vascular disease and/pr pelvic surgery may be at increased risk for tissue erosion.

## Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-09-2016
Enrollment:	50

Type: Anticipated

## Ethics review

Positive opinion

Date: 27-07-2016

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	NL5760
NTR-old	NTR6002
Other	NL55843.100.15 ; AFMPS/80M0633 : 1001-019

## Study results

### Summary results

Not applicable