NeoTract, Inc. UroLift® System
Executive Protocol Summary

Urodynamic Feasibility Study (UDS)

Clinical Protocol Number: CP00009, Rev B
08 October 2018
NCT Number: NCT04271020

Sponsored by:
NeoTract, Inc., a wholly owned subsidiary of
Teleflex®, Inc.
Interventional Urology

PROTOCOL SUMMARY

Study Title	Urodynamic Feasibility Study (UDS)
Device Name and Indications for Use	NeoTract® UroLift® System UL400. This device was cleared for marketing in the USA on September 13, 2013. The UroLift System is indicated for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH), including lateral and median lobe hyperplasia in men 45 years of age or older.
Study Goals	• To prospectively collect urodynamic data prior to, and 3 months after PUL, with the UroLift System, and to assess the impact of the PUL procedure on prostatic obstruction, bladder health and other urodynamic parameters. • To obtain evidence which may support the design of an expanded study.
Subject Population	10 to 20 males over the age of 45, diagnosed with symptomatic benign prostatic hyperplasia (BPH) and intended for PUL procedure with the UroLift System will be enrolled at a single center. Since this is the first study to assess the impact of PUL procedure using pressure flow studies, the population is planned to be similar to the population studied in the LIFT Study.
Study Design	This is a prospective, non-randomized, single-arm, single-center study. This is the first exploratory study of the impact of PUL as measured by pressure flow urodynamic testing (UDS). UDS will be performed at screening and at the 3-month follow-up visits. UDS will include an assessment of obstruction and bladder health as measured by Qmax (maximum urinary flow rate) and Pdet (detrusor pressure) at Qmax, and Pdetmax (maximum voiding pressure), as well as capturing all other standard urodynamic parameters. UroCuff as an alternative form of urodynamics testing will be an optional test performance at baseline and at 3M follow-up. In addition, standard BPH measures such as symptoms, qualify of life, uroflowmetry and post void residual will be evaluated at the follow-up visits. The analysis of the 3-month data is intended to evaluate the possibility of expanding the scope of the study. There will be no formal hypothesis testing.

Study Title	Urodynamic Feasibility Study (UDS)
Inclusion Criteria	• Male gender • Diagnosis of symptomatic BPH • Age ≥ 45 years • International Prostate Symptom Score (IPSS) ≥ 13 • Peak urine flow rate ≤ 12 ml/sec, voided volume ≥ 125 ml • Prostate volume ≤ 80 cc per ultrasound
Key Exclusion Criteria	Key exclusion criteria are listed below. ***See Section 6.3 for the full, detailed list of selection criteria.*** Subjects will be excluded for any of the following: • In current urinary retention • Post void residual (PVR) urine > 250 ml • Have obstructive or protruding median lobe of the prostate • Active urinary tract infection at time of treatment • Current gross hematuria • Previous BPH surgical procedure • Previous pelvic surgery or irradiation • History of neurogenic or atonic bladder • Stress urinary incontinence • Biopsy of the prostate within the past 6 weeks • History of prostate or bladder cancer • Elevated PSA without ruling out prostate cancer • History of compromised renal function or upper tract disease • Known coagulopathies or subject on anticoagulants or antiplatelets other than aspirin ≤ 100 mg (unless antiplatelets are withheld minimum 3 days prior to procedure) • Use of medications known to affect urological function unless washed-out (see protocol list) • Cystolithiasis within the prior 3 months • History of co-morbidities that would affect having an elective urological procedure including: prostatitis, conditions that preclude the insertion of the UroLift System • A known allergy to nickel, titanium, or stainless steel • Unable or unwilling to complete all required questionnaires and follow up assessments • Unable or unwilling to sign informed consent form • Currently enrolled in any other investigational clinical research trial that has not completed the primary endpoint.

Anticipated Study Duration	
Protocol Completion	August 2018
IRB Submission	August 2018
IRB Approval	September 2018
First Patient In (FPI)	September 2018
Last Patient In (LPI)	February 2019 (20 subjects)
3-month Analysis	May 2019
Study Close	June 2019

1 STUDY DESIGN

1.1 Study Objectives

The aim of this feasibility study is to determine the impact of PUL using the UroLift System on standard pressure flow measures for men with BPH. Feasibility and safety objectives include:

- Feasibility – Assess changes in obstruction and bladder health after PUL with the UroLift System.
- Safety- Determined by the absence of any investigator-reported serious adverse events (SAEs) associated with the device or procedure

1.2 Study Design

This is a prospective, non-randomized, single- arm, study. This is the first exploratory study of the impact of PUL as measured by pressure flow, urodynamic testing (UDS). UDS will be performed at screening and the 3-month follow-up visits and will include an assessment of obstruction and bladder health as measured by Qmax and Pdet@Qmax, and by Pdetmax, and other standard urodynamic parameters. Investigators have the option to use UroCuff, an alternative urodynamic test.

In addition, standard BPH measures such as symptoms, qualify of life, uroflowmetry, and post void residual will be evaluated at screening and at the follow-up visits. The analysis of the 3-month data is intended to evaluate the possibility of expanding the scope of the study.

2 ENROLLMENT CRITERIA

2.1 Inclusion Criteria

Subjects enrolled in this clinical study must meet all the following criteria:

1. Male gender
2. Diagnosis of symptomatic BPH

3. Age ≥ 45 years
4. International Prostate Symptom Score (IPSS) ≥ 13
5. Peak urine flow rate ≤ 12 ml/sec on a voided volume ≥ 125 ml
6. Prostate volume to ≤ 80 cc per ultrasound

2.2 Inclusion Criteria

Subjects will be excluded from the study if any of the following conditions apply:

1. Current urinary retention
2. Post void residual (PVR) urine > 250 ml
3. Have an obstructive or protruding median lobe of the prostate
4. Active urinary tract infection at time of treatment
5. Current gross hematuria
6. Previous BPH surgical procedure
7. Previous pelvic surgery or irradiation
8. History of neurogenic or atonic bladder
9. Stress urinary incontinence
10. Biopsy of the prostate within the past 6 weeks
11. Life expectancy estimated to be less than 1 year
12. History of prostate or bladder cancer
13. Elevated PSA without ruling out prostate cancer
14. History of compromised renal function or upper tract disease
15. Known coagulopathies or subject on anticoagulants or antiplatelets other than aspirin ≤ 100 mg (unless antiplatelets are withheld minimum 3 days prior to procedure)
16. Use of the following medications pre-screening (uroflow, questionnaires):
    - Within 4 months of baseline assessment: estrogen, any drug producing androgen suppression, or anabolic steroids
    - Within 3 months of baseline assessment: 5-alpha-reductase inhibitors
    - Within 2 weeks of baseline assessment: alpha-blockers, gonadotropin-releasing hormonal analogs, anticholinergics or cholinergic medication or phenylephrine, pseudoephedrine, or imipramine medications
    - Within 1 week of baseline assessment, unless documented on stable dose for ≥ 6 months: beta blockers, antidepressants, anticonvulsants, and antispasmodics
17. Cystolithiasis within the prior 3 months
18. History of co-morbidities that would affect having an elective urological procedure including: prostatitis, conditions that preclude the insertion of the UroLift System.
19. Other co-morbidities that could impact the study results such as:
    - Severe cardiac arrhythmias uncontrolled by medications or pacemaker
    - Congestive heart failure NYHA III or IV
    - History of uncontrolled diabetes mellitus

- Significant respiratory disease in which hospitalization may be required
- Known immunosuppression (i.e. AIDS, post-transplant, undergoing chemotherapy)

20. A known allergy to nickel, titanium, or stainless steel
21. Unable or unwilling to complete all required questionnaires and follow up assessments
22. Unable or unwilling to sign informed consent form
23. Currently enrolled in any other investigational clinical research trial that has not completed the primary endpoint.

Table 1 : Schedule of Procedures

Summary of Procedures				
Tests & Assessments	**Screening**	**Procedure through Release**	**1-3 Day Visit**	**3 Month Visit (± 7 days)**
Informed Consent	X			
Medical History, including Sexual Function and Catheter Use	X			
Questionnaires				
Urinary Symptoms	X			X
Patient Satisfaction				X
ICIQ-UI Short Form	X			If indicated
Testing Procedures				
UroLift Procedure		X		
Pressure Flow Studies	X			X
UroCuff Test (optional)	X			X
Flexible Cystoscopy with Video	X			
Uroflowmetry	X		X	X
PVR	X		X	X
PSA	X			
UA	X	X	X	X
Urine Culture & Sensitivity	X		If indicated	If indicated
TRUS or Pelvic Ultrasound	X	X		
Review any changes or updates to concomitant medications, adverse events or interventions				
Concomitant Medications	X			X
Adverse Events			X	X
Intervention				X

3 STATISTICAL METHODS

Descriptive reports will be provided for this preliminary evaluation. Data will be expressed as the mean ± SD for continuous variables and as frequencies for categorical variables.

3.1 Sample Size Justification

As this is a feasibility study, a formal sample size calculation is not required. However, we estimate that the number of participants required to get an initial assessment of urodynamic parameters pre and post PUL with UroLift will be between 10 and 20.

3.2 Study Objectives

The aim of this feasibility study is to determine the impact of PUL using the UroLift System on standard pressure flow measures for men with BPH. Feasibility and safety objectives include:

- Feasibility – Assess changes in obstruction and bladder health after PUL with the UroLift System.
- Safety – Determined by the absence of any investigator-reported serious adverse events (SAEs) associated with the device or procedure.

3.3 Statistical Methods

No statistical hypothesis will be tested. Descriptive reports will be provided for this preliminary evaluation. Data will be expressed as the mean ± SD for continuous variables and as frequencies for categorical variables.

4 ANALYSES

This is the first exploratory study of the impact of PUL as measured by pressure flow, urodynamic testing (UDS). UDS will be performed at screening and the 3-month follow-up visits and will include an assessment of obstruction and bladder health as measured by Qmax and Pdet@Qmax, and by Pdetmax, and other standard urodynamic parameters. Investigators have the option to use UroCuff, an alternative urodynamic test.

In addition, standard BPH measures such as symptoms, qualify of life, uroflowmetry, and post void residual will be evaluated at screening and at the follow-up visits. The analysis of the 3-month data is intended to evaluate the possibility of expanding the scope of the study.

4.1 Adverse Events

Adverse events will be summarized by overall adverse events (AEs), severe AEs (grade 3 or higher on CTCAE scale), AEs related to device and/or procedure, serious adverse events (SAEs), and SAEs related to device and/or procedure separately, and UADEs.

4.2 Interim Analysis

The Urodynamics Feasibility Study will enroll at least 10 patients and then an interim analysis of the urodynamic parameters may be conducted.