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Study Title: Modern Urodynamics System Efficacy (MUSE) Study

NCT: NCT05959655

Date of Document: 2023-06-28

1 Protocol Synopsis

Study Title	Modern Urodynamics System Efficacy
Short Title	MUSE Study
Study Sponsor	Bright Uro
Protocol Number	CIP-0005
Study Objective(s)	The objectives of the present study are to evaluate the feasibility, efficacy, and safety of the GUS for use in the clinic to collect vesical pressure data.
Study Design	This is a prospective, observational trial collecting vesical pressure (Pves) and flow from the GUS and cUDS system in patients with Lower Urinary Tract Symptoms (LUTS).
Phase	Phase 0
Estimated Study Period	Up to 24 months
Investigational Devices	Glean Urodynamics System (GUS)
Indications for Use/Intended Use	Indications for Use: The GUS is indicated for standard Urodynamic tests such as Uroflowmetry (UF), Cystometrogram (CMG), Urethral Pressure Profile (UPP), and Micturition Studies (MS). Intended Use: The GUS is a Urodynamic Analyzer system that is intended to quantify the pressure characteristics of the lower urinary tract. The system can be used to perform standard Urodynamic tests such as UF, CMG, UPP, and MS. The major application of Urodynamics is the diagnosis of uncontrolled loss of urine (incontinence), abnormal urinary retention, or neurological cases of Micturition disorder. The device is intended to be used as medical diagnostic equipment.
Number of Subjects	Up to 50 subjects will be enrolled. Assuming a ~20% dropout rate, we expect 40 subjects (20 males and 20 females) to complete the study.
Duration of Study and Follow-up	Each subject will be in the study for up to 24 hours to complete ambulatory GUS.
Study Population	Patients with Lower Urinary Tract Dysfunction (LUTD) who are scheduled for cUDS studies.
Study Site(s)	Up to 6 sites in the United States
Inclusion Criteria	1. Male or female patient must be ≥ 18 years of age 2. Patient must have a diagnosis of LUTD 3. Patient must be scheduled for or recommended for cUDS 4. Patient is able to tolerate 18Fr catheterization 5. Patient or patient's legally authorized representative is able to provide informed consent
Exclusion Criteria	1. Pregnant (as confirmed by urine pregnancy test) or breastfeeding, pregnant within the past 6 months or intend to become pregnant during the study period. 2. Patient has a symptomatic UTI based on CDC guidance (see below) 3. Subjects who, at the principal investigator's determination, would not be appropriate for this study.
Experimental Procedures	1. Patient screened for eligibility and enrolled at the discretion of the principal investigator. 2. A urinalysis (if positive, urine culture), uroflowmetry, and post-void residual (PVR) will be recorded prior to beginning the study. 3. At the first clinic visit, a urine sample will be collected for urinalysis and urine culture prior to any UDS procedures.

	4. Patient is prepared for cUDS per standard of care 5. Clinician will perform standard cUDS cystometry and pressure-flow studies per standard of care including uroflowmetry and PVR. 6. Upon completion of cUDS, the cUDS catheters are removed to allow for insertion of the Glean Sensor. 7. Clinician will gather GUS package and remove sterile pouch from outer packaging. 8. Clinician will open the Glean Clinician App on the mobile device and initiate a new patient Sensor Insertion. The tablet will prompt the clinician to scan the QR code of the GUS. 9. Clinician will scan the QR code through the transparent pouch of the packaging and pair Sensor. 10. Once paired, the Clinician removes inner packaging from sterile pouch using aseptic techniques and places it on a flat surface. 11. The Clinician prepares for aseptic insertion. 12. The Clinician instills lubricant into urethra. For patients with hypersensitivity to pain and sensor insertion, a lubricant with a local anesthetic (e.g., lidocaine) can be applied 5-10 minutes prior to cUDS catheter insertion. 13. Clinician applies lubricant to the Glean Sensor and the tip of the Glean Insertion Sheath while still in the inner packaging. 14. Clinician draws the Sensor into insertion position within the Insertion Sheath by pulling on the removal string from the proximal end of the Insertion Sheath. When positioned correctly, the Sensor will protrude from the distal end of the Insertion Sheath (no more than 1 cm). 15. The Clinician then uses the Insertion Sheath to place the Sensor in bladder. 16. The Clinician confirms Sensor's placement and removes Insertion Sheath. 17. A removal string is taped to patient's body (e.g., thigh, perineum). 18. Patient is asked to perform the following actions: sit up, stand, bend over, twist from one side to the other, jump (if possible), squat (if possible), walk (if possible), cough, and perform Valsalva maneuver ("bear down"). 19. The Patient is then trained to use the Patient Application. 20. In clinic ambulatory GUS is then collected. The patient can dress and leave the procedure room. The patient is encouraged to drink fluids to fill their bladder and to log bladder sensations using the Patient Application. 21. During this period, the patient will complete study surveys. 22. Upon logging sensation of a Strong Desire to Void (SDV), the patient will report back to the clinical staff to void using the Uroflowmeter. 23. Clinician will use the clinician tablet to scan the QR code on the clinic uroflowmeter and pair the clinic Uroflowmeter with the appropriate patient Sensor. 24. The patient will be instructed to void using the clinic Uroflowmeter and PVR will be measured. 25. Upon completion of void, the Uroflowmeter will transfer data to the Clinician App and data will be transferred to the Bright Uro servers. 26. The clinician will remove the Sensor by pulling on the removal string 27. The patient will then be discharged from the study.
Study Endpoints	<u>Baseline Characteristics and Demographics (obtained from EMR or patient chart):</u> Age, sex, prior urological conditions, reason for UDS, LUTD-related medications <u>Primary Endpoints:</u> Success of Glean sensor insertions and removals, subjects experiencing a device-related Serious Adverse Event (SAE), and subject exhibiting compliance in terms of device and voiding diary usage. <u>Secondary Endpoints</u>: Participant-reported outcomes (e.g., comfort, ease of use), successful transfer of GUS data from devices to clinician App and clinician web portal for clinician review.
Analyses	Success of Glean sensor insertions and removals will be calculated as percent of insertions and removals deemed successful by the clinician and subject.

	Safety will be reported as the percent of subjects experiencing a device-related SAE. Rates of SAEs will be calculated on a per-subject, per-event, or per-person-year of follow-up basis. Exact binomial confidence intervals will be calculated for subject-based or event-based rates. Likert scale outcomes will be summarized using frequencies and distributional statistics with binomial or normal approximation-based confidence intervals.
Study and Data Management	Bright Uro 120 Vantis Drive, Suite 440 Aliso Viejo, CA 92656 USA Telephone: 470.222.5323 Fax: 949.998.4731 clinical@brighturo.com
Safety Monitoring	Site Investigators