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Transurethral Thermodilatation versus Prostatic Urethral Lift for Moderate-to-Severe BPH: A Randomised Controlled Non-Inferiority Trial (THRIVE)

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SUBJECT INFORMATION SHEET AND INFORMED CONSENT FORM

Study Title:
Transurethral Thermodilatation versus Prostatic Urethral Lift for Moderate-to-Severe BPH: A Randomised Controlled Non-Inferiority Trial (The THRIVE Study)

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Your participation in this study is entirely voluntary. Please read this information sheet carefully before deciding whether to take part. You are welcome to ask questions at any time. You may withdraw from the study at any stage without giving any reason, and without any effect on your current or future medical care.

PART A: SUBJECT INFORMATION SHEET

1. Introduction and Purpose of the Study

You have been diagnosed with benign prostatic hyperplasia (BPH) — an enlarged prostate gland — which is causing bothersome urinary symptoms such as a weak stream, needing to strain, going frequently, or getting up at night to pass urine. Your symptoms have not been adequately controlled by medication, or you have not tolerated the medications, and you are now being considered for a minimally invasive procedure.

We are inviting you to take part in a clinical research study called the THRIVE trial. The aim is to compare two established, minimally invasive office procedures for BPH — Prolieve® thermodilatation and UroLift® prostatic urethral lift — to find out whether they are equally effective at relieving urinary symptoms. Both procedures are already approved by the FDA; this study is the first randomised trial to compare them head-to-head.

We aim to enrol 150 men aged 50 to 80 years in Hong Kong (Queen Mary Hospital) over approximately 24 months.

2. Why Am I Being Invited?

You are being invited because you have moderate-to-severe urinary symptoms due to BPH that have not been adequately controlled with medication, and because you meet the medical criteria for both procedures. Your doctor has reviewed your test results and considers you a suitable candidate.

3. What Are the Two Procedures Being Compared?

Procedure 1 — Prolieve® Transurethral Thermodilatation ("Prolieve")

The Prolieve system uses a special treatment catheter (thin tube) inserted through your urethra (the urine passage) into the prostate under local anaesthetic jelly — no needle, no injection, and no operating theatre are required. The procedure takes about 45 minutes in the outpatient clinic. The device simultaneously uses gentle microwave heat and a small balloon to open the blocked channel and to cause gradual shrinkage of the overgrown prostate tissue over the following weeks. You will be awake throughout. After the procedure, you will rest for 1 to 2 hours and, if you can pass urine satisfactorily, you will go home the same day.

Procedure 2 — UroLift® Prostatic Urethral Lift ("UroLift")

UroLift uses a small telescope (cystoscope) passed through the urethra to place a few tiny permanent metallic anchors that hold the enlarged prostate lobes apart, physically opening the urethral channel without removing or destroying any tissue. The procedure takes approximately 30 minutes, under a local anaesthesia (local anaesthetic injection near the prostate). You will also go home the same day.

4. What Will Happen If I Join the Study?

If you agree to take part and sign the consent form, a computer will randomly assign you (like a coin toss) to receive either Prolieve or UroLift. You will have an equal (50:50) chance of receiving either procedure. Neither you nor your doctor can choose which procedure you receive, but both are accepted treatment options for your condition.

Step 1: Screening Visit (up to 4 weeks before your procedure)

Your doctor will review your medical history and perform standard tests to confirm you are suitable, including: a blood test (PSA), urine test, prostate ultrasound scan (TRUS) to measure your prostate size, a urine flow test (uroflowmetry), a bladder scan, and short questionnaires about your urinary symptoms and sexual function. You will also be asked to stop your prostate medication before the procedure: alpha-blocker tablets (e.g., tamsulosin) for at least 2 weeks, and 5-alpha-reductase inhibitor tablets (e.g., finasteride) for at least 4 weeks, so that your symptoms can be measured accurately without medication.

Step 2: Procedure Day — Day 0 (Baseline)

You will be formally enrolled and your assigned procedure will be performed. Your pain during the procedure will be measured on a simple 0–10 pain scale, and the type of anaesthetic used will be recorded. A urine flow test will be repeated 1 to 2 hours after the procedure before you go home. You will be given a short course of anti-inflammatory pain tablets for comfort, and tamsulosin (a prostate relaxant tablet) for 4 weeks to help your urinary symptoms while the treatment takes effect.

Step 3: 1-Month Visit (Day 30 ± 7 days)

You will return to the clinic to complete questionnaires about your symptoms and sexual function, have a urine flow test and bladder scan, and have your tamsulosin stopped. Any side effects or problems will be reviewed. The visit takes around 30 minutes.

Step 4: 3-Month Visit — Primary Endpoint (Day 90 ± 14 days)

This is the most important visit of the study. You will complete the IPSS urinary symptom questionnaire (the primary measurement of the study), have a urine flow test and bladder scan, and have blood tests (PSA) and a prostate ultrasound. Any problems or side effects will be reviewed. The visit takes around 30 minutes.

Step 5: 6-Month Visit (Day 180 ± 14 days)

The same questionnaires, flow test, bladder scan, PSA, and prostate ultrasound as at 3 months. We will also collect information about any further treatment you may have needed and associated costs.

Step 6: 12-Month Visit (Day 365 ± 21 days)

Final study visit: the same assessments as at 6 months. This completes your participation. You will continue to receive standard urology care after the study ends.

All study procedures will be performed at Queen Mary Hospital unless otherwise specified.

5. Summary of Study Visits

Visit	Timepoint	Main Assessments
Screening	Up to 4 weeks before procedure	Medical history, prostate scan (TRUS), PSA, urine flow test, bladder scan, questionnaires (IPSS, IIEF-5), urine culture. Medication washout commenced.
Procedure Day	Day 0	Randomisation, procedure, pain score, anaesthetic type recorded, urine flow test at 1–2 hrs post-procedure.
1-Month	Day 30 ± 7 days	Questionnaires (IPSS, IIEF-5, ejaculation status), urine flow test, bladder scan. Tamsulosin stopped.
3-Month ★ Primary outcome	Day 90 ± 14 days	IPSS (primary endpoint), IIEF-5, ejaculation status, urine flow test, bladder scan, PSA, prostate scan.
6-Month	Day 180 ± 14 days	Questionnaires, urine flow test, bladder scan, PSA, prostate scan. Resource-use data collected.
12-Month	Day 365 ± 21 days	Questionnaires, urine flow test, bladder scan, PSA, prostate scan. End of study participation.

6. How Is This Study Different from My Usual Care?

UroLift is available as standard treatment for BPH in Hong Kong. If you do not join the study, your doctor can still offer you UroLift or other options as part of routine care. The key difference in the study is that you may have a chance to receive Prolieve, and your treatment is decided by random allocation rather than by your or your doctor's preference. You will also have more frequent and standardised assessments than in routine clinic care. Compared to the standard care, there would be 4 more extra visits (1, 3, 6, and 12 months after treatment) if you participate in the study.

7. Potential Benefits

Both procedures have demonstrated meaningful improvements in urinary symptoms in published clinical trials. Regardless of which arm you are assigned to, you are likely to benefit from the procedure, but you will not receive any monetary benefit directly from the study, nor have to pay for participation. However, we cannot guarantee that you will personally benefit, as individual responses to treatment vary. Your participation will also contribute to important scientific evidence to help future patients.

8. Potential Risks and Side Effects

Both procedures are associated with low rates of serious complications. The risks below are the same you would face if you had either procedure outside of the study.

Risks common to both procedures:

- Urinary tract infection (within 30 days): uncommon; treatable with antibiotics.
- Temporary burning or stinging when passing urine (dysuria): common for a few days after the procedure; usually resolves on its own.
- Blood in the urine (haematuria): usually mild and short-lived.
- Difficulty passing urine (urinary retention) requiring a temporary urinary catheter: uncommon; approximately 5–16% depending on the procedure.
- Urgency (sudden urge to rush to the toilet): common in the first few weeks after the procedure; usually resolves.
- Changes to ejaculation (e.g., reduced volume or retrograde ejaculation — semen entering the bladder rather than being ejaculated outwards): reported rarely with both procedures. If preservation of fertility is important to you, please discuss this with your doctor before joining.
- Erectile function: both procedures have low rates of erectile dysfunction (less than 5%) in published trials.

Additional considerations for Prolieve:

- You may feel pressure or mild discomfort from the balloon inflation during the 45-minute procedure; most men tolerate this well with lidocaine gel alone.
- A small temperature monitoring probe is placed in the back passage (rectum) during the procedure as a safety measure; this is generally well tolerated.

Additional considerations for UroLift:

- Permanent implants (small metallic and polymer anchors) remain in the prostate long-term and cannot be removed.
- If a periprostatic nerve block injection is used, you may feel temporary discomfort from the injection.

Your doctor will monitor you closely throughout the study. If you experience any concerning symptoms, contact the study team immediately. If you suffer any study-related injury, you will receive appropriate medical care.

9. Do I Have to Pay? Will I Be Compensated?

You will not be charged for the procedure, study-related tests, or questionnaire assessments if you choose to participate. Prolieve procedure kits are provided free of charge by Medifocus Inc. as an in-kind contribution. You will not receive a payment for joining.

10. Will I Continue to Receive Prolieve Treatment After the Study?

You will not receive the Prolieve® thermodilatation treatment after the study ends, even if you benefited from it. This procedure will only be available to you in the future if it becomes routinely funded or commercially accessible. Once your participation concludes, our team will work with your urologist to transition you back to standard care options that are best suited for your condition.

11. What Happens After the Study?

At the end of your 12-month participation, you will return to routine urology outpatient care. If your symptoms return or worsen, or if you require further treatment, this will be arranged as part of normal clinical care at no additional cost to you.

12. New Information During the Study

If any new information arises that might affect your willingness to continue participating, you will be informed promptly and given the opportunity to reconsider.

13. Is Participation Voluntary? Can I Withdraw?

Participation is entirely voluntary. You may withdraw at any time without giving any reason and without affecting your medical care. Data already collected may be retained for analysis unless you request otherwise.

14. Will My Personal Data Be Kept Confidential?

Dr. John LEUNG and his team are responsible for keeping your personal and study data safe and confidential during and after the study. We will handle and store all information according to the strict Hospital Authority rules on patient privacy. All data will be kept strictly confidential, stored on an encrypted system (REDCap) hosted on University of Hong Kong servers. Only authorised study staff will have access to your identifiable data. You will be identified only by a study number in all records and publications. Your personal and study data in this study will be kept for 10 years after it's completion.

Due to clinical safety concern, your current or former participation in this study will be documented in your medical record. You have the rights of access to personal data and publicly available study results, if and when needed. Under the laws of Hong Kong (in particular the Personal Data (Privacy) Ordinance, Cap 486), you enjoy or may enjoy rights for the protection of the confidentiality of your personal data, such as those regarding the collection, custody, retention, management, control, use (including analysis or comparison), transfer in or out of Hong Kong, non-disclosure, erasure and/or in any way dealing with or disposing of any of your personal data in or for this study. For any query, you should consult the Privacy Commissioner for Personal Data or his/her office (Tel No. 2827 2827) as to the proper monitoring or supervision of your personal data protection so that your full awareness and understanding of the significance of compliance with the law governing privacy data is assured. By consenting to participate in this study, you expressly authorise:

- the principal investigator and his research team and the ethics committee(Institutional Review Board of the University of Hong Kong/ Hospital Authority Hong Kong West Cluster)

responsible for overseeing this study to get access to, to use, and to retain your personal data for the purposes and in the manner described in this informed consent process; and

- the relevant government agencies (e.g. the Hong Kong Department of Health) to get access to your personal data for the purposes of checking and verifying the integrity of study data and assessing compliance with the study protocol and relevant requirements.

15. Study Funding and Conflicts of Interest

This is an investigator-initiated study. The University of Hong Kong (HKU) funds this study and is solely responsible for all research decisions, data handling, analysis, and publication—ensuring the study stays independent and unbiased. Prolieve procedure kits are provided free of charge by Medifocus Inc. as an in-kind device contribution; no other commercial funding is received from Medifocus Inc. or Teleflex (the maker of UroLift). All investigators have declared their conflicts of interest.

16. Who Has Reviewed This Study?

This study has been reviewed and approved by the Institutional Review Board of The University of Hong Kong / Hospital Authority Hong Kong West Cluster (HKU/HA HKW IRB). If you have questions about your rights as a research participant, you may contact the IRB at:

Tel: 2255 4086 Email: hkwirb@ha.org.hk

17. Contact for Further Information or Emergencies

Dr. Leung Shung Lai John
Department of Surgery, Queen Mary Hospital
Tel: 852-2255-4852

Upon signing the Informed Consent Form, you will receive a signed copy of this Information Sheet and Consent Form for your own records.

PART B: SUBJECT INFORMED CONSENT FORM

Transurethral Thermodilatation versus Prostatic Urethral Lift for Moderate-to-Severe BPH: A Randomised Controlled Non-Inferiority Trial (The THRIVE Study)

Centre: Department of Surgery, Queen Mary Hospital
Department of Surgery, LKS Faculty of Medicine, The University of Hong Kong

Principal Investigator: Dr. Leung Shung Lai John Tel: 852-2255-4852

I confirm that I have read and understood the Subject Information Sheet for the above study, and that I have had the opportunity to ask questions. My questions have been answered to my satisfaction. I understand that my participation in this study is entirely voluntary, and that I am free to withdraw at any time without giving any reason and without any effect on my medical care or legal rights. I understand that this study involves random assignment (by computer) to one of two established prostate procedures (Prolieve® or UroLift®), and that neither I nor my doctor can choose which I receive. I understand that I will be required to temporarily stop my prostate medications before the procedure, and to attend follow-up visits at 1, 3, 6, and 12 months after the procedure. I understand that I will not continue to receive Prolieve® thermodilatation after the study ends (even if I benefited from it) unless it becomes commercially or publicly funded in the future, and that I will be transitioned to standard care options at the conclusion of my participation, and that stopping the study treatment will not negatively affect my disease management. I understand that my relevant medical records may be accessed by the study team, research auditors, members of the HKU/HA HKW IRB, and relevant regulatory authorities to verify study data and monitor compliance with the study protocol, to the extent permitted by applicable laws and regulations. I understand that my personal data will be handled in accordance with the Hong Kong Personal Data (Privacy) Ordinance (Cap. 486), and that I will be identified only by a study number in all records and publications. I understand that study results may be published in scientific journals and presented at conferences, but that my personal identity will not be disclosed. I consent to my data being retained for analysis if I choose to withdraw from the study, unless I specifically request that my data be removed.

☐ I agree to take part in the above study.

Name of Subject	**Date**	**Signature**

Name of Researcher	**Date**	**Signature**