INFORMED CONSENT FORM (ICF)

Official Title: Evaluation of the Effect of Catheter Duration on Prostate Laser Enucleation Surgery Outcomes in Patients with Indwelling Catheters Due to Urinary Retention: A Multicenter Study of the Minimally Invasive Urology Society

NCT Number: Not yet assigned

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Principal Investigator: Dr. Suleyman Oner

Institution: Eskisehir Osmangazi University Faculty of Medicine, Department of Urology, Eskisehir, Turkey

Participating Centers: MIUS Affiliated Academic and Community Urology Centers

Version: 1.1

Local Ethics Committee Approval Number:

E-25403353-050.04-260029122

Patient Information and Informed Consent Form

Study Title

Evaluation of the Effect of Catheter Duration on Laser Enucleation Surgery Outcomes in Patients with Indwelling Catheters Due to Urinary Retention: A Multicenter Study of the Minimally Invasive Urology Society

Introduction

You are being invited to participate in a medical research study. Before you decide, it is important for you to understand why the study is being conducted and what your participation will involve. Please take the time to read the following information carefully.

Purpose of the Study

This study aims to evaluate how the length of time a patient spends with a urinary catheter before surgery affects the recovery of urinary functions. Specifically, we are comparing outcomes between patients with short-term catheter use versus those with prolonged catheter use prior to surgery. The study focuses on functional measures such as the International Prostate Symptom Score (IPSS), urinary flow rate (Qmax), and post-void residual volume (PVR).

Why Have I Been Invited?

You have been invited because you are scheduled for laser enucleation of the prostate (HoLEP, ThuLEP, or ThuFLEP) due to benign prostatic obstruction and are currently using a urinary catheter. Your data will help us determine the optimal timing for surgery for future patients.

Do I Have to Take Part?

Participation is entirely voluntary. If you decide not to participate, your medical care and relationship with your doctors will not be affected in any way. You are free to withdraw at any time.

What Will Happen if I Take Part?

If you agree to take part, your routine medical information including your medical history, surgical details, and follow-up results at the 3rd month will be recorded in a secure database. No additional procedures, extra hospital visits, or experimental interventions are required beyond your standard surgical care.

Possible Risks and Benefits

There are no direct medical risks to you, as the study only involves recording routine clinical data. While there may be no direct benefit to you personally, the information gathered will contribute to improving surgical protocols and care for patients with similar conditions.

Confidentiality

All information will remain strictly confidential. Your data will be anonymized (your name and identifiers removed) before analysis. Results will only be reported in aggregate form, ensuring no individual can be identified.

Use of Data

Your anonymized data may be used for future scientific analyses related to BPO surgeries. Any such analyses will be approved by an ethics committee if required. Future studies using this registry data will be registered separately on ClinicalTrials.gov with their own protocols.

Contact Information

If you have any questions about this study, please contact Dr. Suleyman Oner or your attending urologist.

Consent Statement

I have read and understood the information provided above. I have had the opportunity to ask questions, and they have been answered to my satisfaction. I understand that my participation is voluntary and that I may withdraw at any time.

Participant's Name:

Signature: Date:

Investigator's Name:

Signature: Date: