

Clinical Study Cover Page

Official Study Title:

Evaluation of the Association Between Uroflowmetry Curve Patterns and IPSS Domains in Men With Lower Urinary Tract Symptoms

Brief Title:

Uroflowmetry Curve Types and IPSS in Men With LUTS (UROFLOW-IPSS)

NCT Number:

[Not yet assigned]

Unique Protocol ID:

MAR.UAD.0022

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May 1, 2025

VOLUNTARY PARTICIPANT INFORMATION AND CONSENT FORM

Study Title:

Evaluation of the Association Between Uroflowmetry Curve Patterns and IPSS Domains in Men With Lower Urinary Tract Symptoms

Principal Investigator:

Prof. Dr. Haydar Kamil Çam

Co-Investigator:

Dr. Günal Özgür

Information About the Study:

This study aims to evaluate urinary symptoms in men and how they relate to urinary flow patterns and symptom scores. No treatment will be applied as part of the study. The study is based entirely on questionnaires and existing clinical data. Your participation is entirely voluntary.

If you agree to participate, your age, height, weight, medical history, medications, and urinary symptoms will be recorded. You will also complete the IPSS (International Prostate Symptom Score) questionnaire and the Quality of Life question. In addition, existing clinical data such as uroflowmetry test results, creatinine, eGFR, and prostate volume will be recorded from your medical file.

All data will be collected at a single time point. No blood or urine samples will be taken specifically for this study. There are no physical risks associated with participating in this research. The results will help improve understanding and management of urinary symptoms in men.

The study is expected to last approximately 6 months and will include about 250 participants. It will be conducted solely at Marmara University, Faculty of Medicine, Department of Urology.

Your Rights:

You are free to refuse participation. If you choose not to participate or decide to withdraw later, this will not affect your medical care in any way. You may leave the study at any time without giving a reason.

You will not incur any expenses or receive any payment related to your participation in this study. Your data will be used only for this research and will remain confidential in accordance with institutional and ethical regulations.

If you experience any health issues during the study, appropriate medical attention will be provided, and you will not bear any cost for such care.

For any questions related to the study, you may contact Dr. Günal Özgür (Phone: +90 535 784 9485, Email: gunalozgur91@hotmail.com).

PARTICIPANT STATEMENT:

I was informed by Dr. Günal Özgür about a clinical research study to be conducted at Marmara University Pendik Training and Research Hospital, Department of Urology. I received written and verbal information about the study. I had the opportunity to ask questions and received satisfactory answers. I voluntarily agree to participate in this research. I understand that I may withdraw from the study at any time. I will receive a copy of this signed form.

VOLUNTARY CONSENT SECTION:

Participant Name and Surname:

Signature:

Date: ____ / ____ / ____

Name and Surname of Researcher Providing Explanation:

Signature:

Witness (Name, Surname, Title, Signature):