Cover Letter for Informed Consent Form Submission

Date: June 12, 2024

IRB Reference Number: 0996-2024-LNH-ERC

To:
ClinicalTrials.gov PRS Administrator / Study Registration Officer
National Library of Medicine
U.S. National Institutes of Health

Subject: Cover Letter for Informed Consent Form Submission

Study Title: Randomized Clinical Trial Comparing Alpha-Blocker and Anti-Cholinergic Drug Therapies for Ureteral Stent-Related Symptoms
Principal Investigator: Dr. Fareha Mansoor Khan
Affiliation: Department of Urology, Liaquat National Hospital, Karachi

Dear Sir/Madam,

I am submitting the attached Informed Consent Form (ICF) for the clinical trial titled "Randomized Clinical Trial Comparing Alpha-Blocker and Anti-Cholinergic Drug Therapies for Ureteral Stent-Related Symptoms," currently registered with IRB Reference No. 0996-2024-LNH-ERC. The study has been approved by the Ethical Review Committee of Liaquat National Hospital.

This consent form outlines the study purpose, procedures, risks, benefits, confidentiality safeguards, and voluntary participation statement, in compliance with GCP and the Declaration of Helsinki. It is being submitted to fulfill ClinicalTrials.gov's requirement for transparency and completeness in registered clinical studies.

The NCT number is currently pending and will be updated in the record once assigned.

Please let me know if any further clarification or documentation is required.

Sincerely,

Dr. Fareha Mansoor Khan
Resident, Department of Urology
Liaquat National Hospital, Karachi

INFORMED CONSENT FORM

TITLE OF STUDY: RANDOMIZED CLINICAL TRIAL COMPARING ALPHA-BLOCKER AND ANTI-CHOLINERGIC DRUG THERAPIES FOR URETERAL STENT-RELATED SYMPTOMS

Investigator:

DR FAREHA MANSOOR KHAN,

RESIDENT OF UROLOGY DEPT, LIAQAT NATIONAL HOSPITAL

You are being invited to participate in a clinical research study. Before you decide to participate, it is important that you understand the purpose of the study, what will be asked of you, and the potential risks and benefits. Please take the time to read this form and ask any questions you may have before deciding to participate.

Purpose of the Study:

The purpose of this study is to compare the effectiveness of two different drug therapies, alpha-blockers and anti-cholinergic drugs, in managing symptoms related to the presence of a ureteral stent. Ureteral stents are commonly used in medical practice, and this study aims to determine which treatment is more effective in alleviating associated symptoms, such as pain, urgency, and frequency.

Study Procedures:

If you agree to participate in this study, you will be randomly assigned to one of two groups. Group 1 will receive the alpha-blocker drug, and Group 2 will receive the anti-cholinergic drug.

The assignment to these groups will be determined randomly, and neither you nor the research team will have control over this assignment.

You will be required to take the assigned medication as directed by the study team. Regular follow-up visits will be scheduled to monitor your symptoms, assess any side effects, and adjust the treatment plan if necessary. You may also be asked to provide feedback on your symptoms through a questionnaire.

Risks and Benefits:

There are potential risks and benefits associated with participating in this study. The potential benefits include a better understanding of which treatment is more effective in managing ureteral stent-related symptoms. The information gained from this study may contribute to improvements in the treatment of individuals with ureteral stents.

Potential risks include known side effects associated with the use of alpha-blockers and anti-cholinergic drugs. The research team will provide you with detailed information about these potential side effects during the informed consent process.

Confidentiality:

All information collected during this study will be kept confidential. Your identity will be protected by assigning a unique identification number to your data, and all study records will be stored in a secure location with limited access.

Voluntary Participation:

Participation in this study is voluntary, and you have the right to withdraw at any time without penalty or loss of benefits to which you are otherwise entitled. If you choose to withdraw, it will not affect your relationship with your healthcare provider.

Statement of Consent:

I have read and understood the information provided in this consent form. I have had the opportunity to ask questions, and any questions I have asked, have been answered to my satisfaction. I voluntarily agree to participate in the study.

Participant's Name: _____ Date: _____

Investigator's Signature: _____ Date: _____