Informed Consent

Project Information

Title:

Impact of verbal compared to structured information on patient's anxiety and satisfaction undergoing uroflowmetry

NCT- Number: Not yet allotted

Unique protocol ID (assigned by institutional IRB):
2023-8493-26340

Date: 29/6/2025

Primary Investigator:

Dr. Ramna Nadeem, resident year 3 (PGY 5), Urology, Aga Khan University Hospital (ramna.nadeem@aku.edu)

Co-investigator:

Dr. Muhammad Hammad Ather, Professor of Urology, Department of Surgery, Aga Khan University Hospital. (hammad.ather@aku.edu)

Dr. Nuzhat Faruqui, Assistant Professor, Surgery, Aga Khan University Hospital. (nuzhat.faruqui@aku.edu)

STATEMENT OF COMPLIANCE:
This study complies with the Good Clinical Practice (GCP) Guidelines.

Project Title: Impact of verbal compared to structured information on patient's anxiety and satisfaction undergoing uroflowmetry - a Randomized control trial	Project Number: 8493
ERC Ref No: 2023-8493-26340	Sponsor: NA
Principal Investigator: Dr. Ramna Nadeem, resident year 1 (PGY 3), Urology, Aga Khan University Hospital (ramna.nadeem@aku.edu)	Organization: Aga Khan University Hospital, Karachi, Pakistan.
Location: Section of Urology, Department of Surgery, Aga Khan University Hospital, Karachi, Pakistan.	
Other Investigators: Dr. Muhammad Hammad Ather, Professor of Urology, Department of Surgery, Aga Khan University Hospital. (hammad.ather@aku.edu) Dr. Nuzhat Faruqui, Assistant Professor, Surgery, Aga Khan University Hospital. (Nuzhat.faruqui@aku.edu)	Organization: Aga Khan University Hospital, Karachi, Pakistan.
Location: Section of Urology, Department of Surgery, Aga Khan University Hospital, Karachi, Pakistan.	

"I am Dr. Ramna Nadeem from Section of urology, Department of Surgery, Aga Khan University and doing a research on "Impact of verbal compared to structured information on patient's anxiety and satisfaction undergoing uroflowmetry - a Randomized control trial".

Uroflowmetry is one of initial test used to evaluate lower urinary tract symptoms in person. Lower urinary tract symptoms include increased day time frequency, increased night time frequency, urgency, leakage while have urge, leakage during coughing, poor flow, intermittent stream, delayed start of urination and have sensation of having urine in bladder even after voiding. This test is performed as outpatient and only required full bladder as its pre requisite. Before going for this test patient must be provided adequate knowledge regarding test. This study is basically utilization of two different methods of counselling. It will help in future to guide patients regarding this test more effectively.

1. PURPOSE OF THIS RESEARCH STUDY

- You are being asked to participate in a research study designed to compare effects of two different types of counselling strategies before uroflowmetry. Results of this study will help us to provide more effective guidance to patients regarding this test.

2. PROCEDURES

- Before performing uroflowmtery, information regarding uroflowmetry is provided to all patients. There are different modes of providing information. In this study two methods of counselling are utilized.
  - Verbal counselling
  - Structured counselling (through broucher and video tutorial)
- Each and every participant has equal chances of going in above mentioned groups.
- After counselling a short questionnaire comprising of basic details and anxiety assessment will be filled and then after performing uroflowmetry satisfaction score will be filled. Whole this procedure will take approximately 20-25 minutes.

3. POSSIBLE RISKS OR DISCOMFORT

- No extra investigations will be performed.
- None of the method will cause extra pain or any other symptoms.
- None of the method will change the course of treatment.

4. POSSIBLE BENEFITS

This study may benefit patients in future in getting standardized one method of counselling before uroflowmetry which will improve their satisfaction , reduce their anxiety and by doing this eventually decreasing number of attempts needed for adequate test.

5. FINANCIAL CONSIDERATIONS

- There is no financial compensation for your participation in this research.
- There is no any additional cost burden on patient by participating in this study.
- No cost/part of cost of treatment covered by the study.

6. AVAILABLE TREATMENT ALTERNATIVES

- Standard method of Ureteric access is in lithotomy position. Access in supine position is more recent and the costs as well as the operative time and Radiation exposure in lower as compared to the lithotomy position. There is no added risk of any injury during the procedure.

7. AVAILABLE MEDICAL TREATMENT FOR ADVERSE EXPERIENCES

- None of the method have any additional risks or complications. However if you found to be significantly more anxious you'll be referred to pychologist for proper evaluation and need for any treatment.

8. CONFIDENTIALITY

"Your identity in this study will be treated as confidential. The results of the study, including laboratory or any other data, may be published for scientific purposes but will not give your name or include any identifiable references to you." However, any records or data obtained as a result of your participation in this study may be inspected by the sponsor or by AKU ERC members".

9. TERMINATION OF RESEARCH STUDY

You are free to choose whether or not to participate in this study. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate. There will be no consequences or treatment differences if one is not willing to participate in study.

In addition, your participation in the study may be terminated by the investigator without your consent under any circumstances.

10. STUDY WITHDRAWAL

If any un-expected effects happened on patients during study those will be recorded and if found to be hazardous for patient then study will be withdrawn after reporting effect.

11. AVAILABLE SOURCES OF INFORMATION

- Any further questions you have about this study will be answered by the Investigator.
  Name: Dr. Ramna Nadeem
  Phone Number: 0321-8095545
- Any questions you may have about your rights as a research subject will be answered by:
- Name: Dr. Ramna Nadeem
- Phone Number: 0321-8095545

12. AUTHORIZATION

I have read and understand this consent form, and I volunteer to participate in this research study. I understand that I will receive a copy of this form. I voluntarily choose to participate, but I understand that my consent does not take away any legal rights in the case of negligence or other legal fault of anyone who is involved in this study.

Name of participant:
Date:
Signature of participant:

Signature of Principal Investigator:
Date:

Name and Signature of person obtaining consent:
Date:

Name and Signature of witness:
Date: