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Study Title	Use of Hyoscyamine versus Tamsulosin for Management of Ureteral Stent Irritation
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RESEARCH CONSENT FORM
Use of a Hyoscyamine versus Tamsulosin for Management of Ureteral Stent Irritation
Protocol # 142994
Sponsor: Investigator-Initiated Trial

Investigator:
David Duchene, MD FACS
University of Kansas Medical Center
913-588-1227

- We are asking you to be in a research study
- Research is done to answer a scientific question. Research studies may or may not help the people who participate
- Joining this study is completely voluntary. If you say yes, you can quit the study at any time
- You can still get medical care and other services from the University of Kansas Medical Center even if you are not in the study
- The research team will explain what happens if you decide to join the study. This conversation is called "informed consent"
- Informed consent includes a chance to get your questions answered before you make your decision. Please ask as many questions as you need to.
- This consent form explains the study. Take as much time as you need to decide.
- If you decide to be in the study, you will be asked to sign this form.

This research will take place at the University of Kansas Medical Center (KUMC) with David Duchene, MD as the researcher. About 100 people will be in the study at KUMC.

Why is this study being done?
Ureteral stents are routinely used in a variety of urologic conditions such as kidney stones, upper tract carcinoma, and ureteroscopy. Despite their usefulness, patient often experience uncomfortable stent-related lower urinary tract symptoms such as bladder spasms, urinary frequency and urgency, and pain. Providers routinely prescribe a variety of medications to patients to minimize stent-related discomfort. Two of those such medications are Tamsulosin and Hyoscyamine.

What is the purpose of the study?
The main goal of this study is to compare the drug Hyoscyamine to the drug Tamsulosin in their ability to treat lower urinary tract symptoms in patients with indwelling stents.

How long will I be in the study?
We expect your participation to last about 6 weeks (up to one week for screening and five weeks for follow-up after your surgery) and will include up to one office visit to the clinic. This visit is per standard of care. There will be no study specific visits.

What will I be asked to do?
If you are eligible and decide to participate in this study, you will be asked to do the follow tests and procedures. Below is a table that lists all the procedures you will be asked to complete. After the table you will find more details about the study procedures.

SCHEDULE OF EVENTS					
	Enrollment	Stent Placement	Post-operative Day One	Stent Removal or Post-Operative Day 7	Post-Operative Day 30
Informed Consent	X				
Demographics	X				
Randomization	X				
Drug Diary		X	X	X	
Questionnaire	X		X	X	X

Demographics: You will be asked questions about your health and medical history.

Randomization: You will be randomly assigned (like flipping a coin) to one of 2 groups:

Group 1: Hyosyamine 0.125 mg tablet every four hours as needed

Group 2: Tamsulosin 0.4 mg tablet once a day.

Both you and the investigator will know which group you are assigned too. You will begin to take medication after stent placement. You will be sent home with a standard of care narcotic pain medication as well. If you do not find relief with the medication you were randomized to you will be allowed to receive additional narcotic pain medications or be allowed to take a different medication. Use of Hyoscyamine or Tamsulosin will be stopped once the stent is removed, per standard of care.

Drug Diary: You will be given a drug diary to document use of your study medication as well as other medications you have been taking. You will document medication usage starting the day of stent placement and will stop after your stent has been removed.

Questionnaire: You will be asked to complete a questionnaire regarding your stent or kidney related symptoms at four time points during the trial. The questionnaires can be completed either in person or via an email survey.

What are the possible risks or discomforts?
You might feel inconvenienced by having to answer the questions or embarrassed by some of the questions the researchers may ask you. You are free not to answer the questions. You may also be inconvenienced by having to complete a drug diary.

Hyoscyamine is routinely used in urology practice for stent related irritation. Side-effects include constipation, dry mouth, drowsiness, headaches, or lightheadedness.

Tamsulosin is routinely used in urologic practice for stent related irritation. Side-effects include dizziness (14.9%), nasal congestion (2.2%), temporary loss of consciousness (syncope) (0.2%), and decreased ejaculation volume due to semen entering bladder(retrograde ejaculation)(8.4%). If you get cataract

surgery in the near future you may also be at risk for loss of muscle tone in your eye (intraoperative floppy iris syndrome) (2%).
You are free to stop taking either drug if you experience side effects and your treating provider will prescribe you a new drug based on standard of care practice.

Are there benefits to being in the study?
You may not receive any personal benefit from the study but researchers hope that the information from this research study may be useful in the treatment of other patients that will have ureteral stents placed.

NEW FINDINGS STATEMENT

You will be told about anything new that might change your decision to be in the study. You may be asked to sign a new consent form if this occurs.

Will it cost anything to be in the study?
The study will pay for all study-related services provided during the study. These services include the questionnaire as listed in the consent form. You will be responsible for the cost of study medication. Depending on your insurance one drug may cost more than the other. The surgery for you condition is not part of this study and will be billed to you or your insurance through normal hospital billing practices.

Any other medical visits and procedures you have outside of the study due to other standard of care treatments or other health issues are billable to you or your insurance through normal hospital billing practices. Standard of care means necessary for the care of a medical issue as determined by your doctor and not necessary for this study.

Your insurance may not cover some or all of the standard care services if you are part of a research study. You may want to talk to your insurance company and review your specific benefits and coverage before deciding to participate. You will be responsible for normal co-pays, deductibles and non-covered services that are not the responsibility of the study. Some procedures require pre-certification from your insurance company. Pre-certification is not a guarantee of payment.

You can still be in the study even if your insurance denies coverage for your standard of care treatment or if you are uninsured. The hospital has a financial assistance program which it makes available to all patients who qualify. If your insurance denies coverage and you do not qualify for the financial assistance, you will be charged for all bills that are not the responsibility of the study. The study staff will be able to provide more information to you.

Will I get paid to participate in the study?
There is no payment for this study.

What happens if I get hurt or sick during the study?
If you experience harm or have another problem during this study, you should immediately contact Dr. David Duchene at 913-588-6146. If it is after 5:00 p.m., a holiday, or a weekend, you should call 913-588-5000 and ask for the urologist on call and indicate that you are part of a research study. A member of the research team will decide what type of treatment, if any, is best for you at that time.

If you think you have been harmed as a result of participating in research at the University of Kansas Medical Center (KUMC) or one of its affiliates, you should contact the Director, Human Research Protection Program at Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160. You may also telephone (913) 588-1240.

What other choices do I have?
Participation in this study is voluntary. Deciding not to participate will have no effect on the care or services you receive at the University of Kansas Medical Center.

How will my privacy be protected?
The researchers will protect your information, as required by law. Absolute confidentiality cannot be guaranteed because persons outside the study team may need to look at your study records. All study records will use a unique study ID so as not to disclose personal information. The researchers may publish the results of the study. If they do, they will only discuss group results. Your name will not be used in any publication or presentation about the study.

Your health information is protected by a federal privacy law called HIPPA. By signing this consent form, you are giving permission for KUMC to use and share health information. If you decide not to sign the form, you cannot be in the study.

The researchers will only use and share information that is needed for the study. To do the study, they will collect health information from the study activities and from your medical record. You will be assigned a unique study ID so that the health information collected will not be associated with your name. Your health information will be used at KU Medical Center by Dr. Mirza, members of the research team, the University Hospital Medical Record Department, the KUMC Research Institute, the KUMC Human Subjects Committee and other committees and offices that review and monitor research studies. Study records might be reviewed by government officials who oversee research, if a regulatory review takes place.

All study information that is sent outside KU Medical Center will have your name and other identifying characteristics removed, so that your identity will not be known. Because identifiers will be removed, your health information will not be re-disclosed by outside persons or groups and will not lose its federal privacy protection.

Your permission to use and share your health information remains in effect until the study is complete and results are analyzed. After that time, researchers will remove personal information from study records. The University of Kansas Healthy System Department of Urology retains records for up to 15 years or at the discretion of the principal investigator.

The researchers may publish the results of the study. If they do, they will only discuss group results. Your name will not be used in any publication or presentation about the study.

The researchers may publish the results of the study. If they do, they will only discuss group results. Your name will not be used in any publication or presentation about the study.

How will my research information be used in the future?

Results from this study might be used in the future for other research. If that happens information that could identify you will be removed first. You will not be asked if you agree to the future research that has identifiers removed.

Can I stop being in the study?
You may stop being in the study at any time. Your decision to stop will not prevent you from getting treatment or services at KUMC. The entire study may be discontinued for any reason without your consent by the investigator conducting the study.

You have the right to cancel your permission for researchers to use your health information. If you want to cancel your permission, please write to Dr. Lee. The mailing address is David Duchene, MD, Univeristy of Kansas Medical Center, 3901 Rainbow Boulevard, Kansas City, KS, 66160. If you cancel permission to use your health information, you will be withdrawn from the study. The research team will stop collecting any additional information about you. The research team may use and share information that was gathered before they received your cancellation.

Who can I talk to about the study?
Dr. Duchene or other members of the study team should answer all your questions before you sign this form. They will also tell you if they learn anything new that might affect your decision to stay in the study. You can talk to researchers if you have any more questions, suggestions, concerns, or complaints. If you have questions about your rights as a research subject, or if you want to talk with someone who is not involved in the study, you may call the KUMC Institutional Review Board at (913) 588-1240. You may also write the Institutional Review Board at Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by the U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

CONSENT

Dr. Duchene or the research team has given you information about this research study. They have explained what will be done and how long it will take. They explained any inconvenience, discomfort or risks that may be experienced during this study.
By signing this form, you say that you freely and voluntarily agree to be in this research study. You have read the information and had your questions answered.

You will be given a signed copy of the consent form to keep for your records.

_____

Print Participant's Name

_____ _____ _____

Signature of Participant Time Date

_____

Print Name of Person Explaining Consent

_____ _____

Signature of Person Explaining Consent Date