Perioperative hypogonadism in men undergoing radical cystoprostatectomy for bladder cancer

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RESEARCH CONSENT FORM

Perioperative hypogonadism in men undergoing radical cystoprostatectomy for bladder cancer

Protocol 1.0

You are being asked to join a research study. You are being asked to take part in this study because you are a male patient at the University of Kansas and are scheduling a radical cystectomy (surgical removal of bladder). You do not have to participate in this research study. The main purpose of research is to create new knowledge for the benefit of future patients and society in general. Research studies may or may not benefit the people who participate.

Research is voluntary, and you may change your mind at any time. There will be no penalty to you if you decide not to participate, or if you start the study and decide to stop early. Either way, you can still get medical care and services at the University of Kansas Medical Center (KUMC).

This consent form explains what you have to do if you are in the study. It also describes the possible risks and benefits. Please read the form carefully before deciding about this research.

BACKGROUND

Bladder cancer is the sixth-most common malignancy in the United States. The current standard treatment for invasive bladder cancer is radical cystectomy (RC), a complex operation that requires bladder removal and urinary tract reconstruction using a piece of the small intestine. Furthermore, low testosterone levels are common in male patients with cancer but it is unknown exactly how this relates to bladder cancer progression or treatment. There is a lack of data regarding testosterone response to cystectomy in the time period surrounding surgery. The results of this study will lead to a better understanding of the testosterone response to bladder surgery.

PURPOSE

The goal of this study is to examine the relationship between testosterone level changes around the time of radical cystectomy.

PARTICIPATION/PROCEDURES

If you choose to participate in this study, your testosterone and related hormone levels will be obtained through blood draws at several instances around the time of your bladder surgery. Laboratory draws will occur a total of 4 times: before surgery during your pre-operative clinic appointment, two days after surgery while in the hospital, at your first post-operative visit (2-3 weeks after discharge), and at your three-month follow up clinic appointment. All blood draws will occur when you are having standard of care labs for routine care, in order to avoid extra needle sticks. An additional 5 mL (1 teaspoon) of blood will be drawn at each time point. Your laboratory results will be shared with you. If you are found to have low testosterone levels, you will be provided follow up with a urologist who is fellowship trained in andrology. Further discussion regarding testosterone replacement and follow up of testosterone levels can be discussed at that follow up visit after recovery from surgery.

RISKS

There are minimal risks to participating. Blood draw may result in pain, infection, bruising, and fainting. There may be other risks of the study that are not yet known. If these are discovered, you will be notified.

BENEFITS

Researchers hope that the information from this research study may be useful in the treatment of bladder cancer and low testosterone. By learning more about the bladder cancer, surgery, and testosterone, we may discover better ways to treat or prevent the disease.

ALTERNATIVES

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.

COSTS

During your participation in this study, you will be receiving services that are considered to be both study related and standard of care. Standard of care in this situation means you would have received those services whether you were in the study or not. The study will cover the cost of the research that are not part of the standard of care. The standard of care services will be billed to your insurance through normal hospital billing practices. Your insurance may not cover some or all of the services if you are part of a research study. Pre-certification is not a guarantee of payment. 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. You can still be in the study even if your insurance denies coverage for your standard of care and other routine medical treatment or if you are uninsured. The hospital has a financial assistance program, which it makes available to all patients who qualify. You will be responsible for co-pays deductibles and non-covered services. You can still be in the study if you insurance denies coverage for your study related and standard services or if you are uninsured. The hospital has financial assistance program, which it makes available to all patients who qualify. If you do not qualify for financial assistance you will be responsible for all bills both study related and standard of care related. The study staff will be able to provide you additional information.

INSTITUTIONAL DISCLAIMER STATEMENT

If you think you have been harmed as a result of participating in research at the University of Kansas Medical Center (KUMC), you should contact the Director, Human Research Protection Program, Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160.

Under certain conditions, Kansas state law or the Kansas Tort Claims Act may allow for payment to persons who are injured in research at KUMC.

CONFIDENTIALITY AND PRIVACY AUTHORIZATION

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. 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 HIPAA. By signing this consent form, you are giving permission for KUMC to use and share your 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 may be identified by information such as name, address, phone, date of birth, social security number, or other identifiers. Your health information will be used at KU Medical Center by Dr. Jeffery Holzbeierlein, members of the research team, 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. Your permission to use and share your health information remains in effect until the study is complete and the results are analyzed. After that time, researchers will remove personal information from study records.

All study information that is sent outside KU Medical Center will have my name and other identifying characteristics removed, so that my identity will not be known. Because identifiers will be removed, my 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 the results are analyzed. After that time, researchers will remove personal information from study records.

QUESTIONS

Before you sign this form, Dr. Holzbeierlein or other members of the study team should answer all your questions. You can talk to the researchers if you have any more questions, suggestions, concerns or complaints after signing this form. If you have any 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 Human Subjects Committee at (913) 588-1240. You may also write the Human Subjects Committee at Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160.

SUBJECT RIGHTS AND WITHDRAWAL FROM 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. Jeffery Holzbeierlein. The mailing address is Dr. Jeffery Holzbeierlein, University 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.

CONSENT

Dr. Holzbeierlein or the research team has given you information about this research study. This form has

explained what will be done and how long it will take. It has explained any inconvenience, discomfort or risks that may be experienced during this study.

By signing this form, you say that you freely and voluntarily consent to participate in this research study. You have read the information and had your questions answered. You will receive a signed copy of this consent form as well.

_____
Print Participant's Name

_____
Signature of Participant Time Date

_____
Print Name of Person Obtaining Consent

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Signature of Person Obtaining Consent Date