The University of New Mexico Health Sciences Center
Consent and Authorization to Participate in a Research Study

Key Information for CLN-UP: ChLorhexidine gluconate versus povidoNe iodine for vaginal surgical preparation for Urogynecological Procedures

You are being invited to take part in a research study about surgical preoperative (pre-surgery) vaginal skin preparations (soaps) for urogynecologic surgery.

WHAT IS THE PURPOSE, PROCEDURES, AND DURATION OF THE STUDY?

By doing this study, we hope to learn whether one of two different types of pre-surgery skin soaps (povidone iodine and chlorhexidine gluconate) is worse than the other for preventing infection. Your participation in this research will last about 6 weeks.

WHAT ARE THE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

Both of these soaps are routinely used. Participation in this study may help find out if the soaps are similar at preventing infection. For a complete description of benefits, refer to the Detailed Consent.

WHAT ARE THE KEY REASONS YOU MIGHT NOT CHOOSE TO VOLUNTEER FOR THIS STUDY?

In some cases, there can be allergic reactions to either of the soaps used for surgery. For a complete description of the risks, refer to the Detailed Consent/Appendix.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer

If you are an employee, if you decide not to take part in this study, your choice will have no effect on your employment status.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of this study is Peter Jeppson, MD of the University of New Mexico Health Sciences Center, Department of Obstetrics and Gynecology. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, please contact 505-967-8428.

If you have any questions or concerns about your rights as a volunteer in this research, contact staff in the University of New Mexico Health Sciences (UNMHSC) Human Research Review Committee (HRRC) between the business hours of 8AM and 5PM, Mountain Standard Time (MST), Monday-Friday at 505-272-1129.

CLN-UP: ChLorhexidine gluconate versus povidoNe iodine for vaginal surgical preparation for Urogynecological Procedures

10/22/2020

Purpose and General Information

You are being asked to participate in a research study that is being done by Dr. Peter Jeppson, who is the Principal Investigator, and Associates, from the Department of Female Pelvic Medicine and Reconstructive Surgery. This research is studying surgical preoperative vaginal skin preparations for urogynecologic surgery.

Urogynecologic problems are commonly treated with surgeries that require cleansing of the vagina with soaps just prior to starting surgery to decrease the risk of infections. These surgeries may include a vaginal approach, or include surgery in the vagina. There are several different kinds of vaginal skin preparations that are used just prior to surgeries in the operating room to decrease the amount of bacteria in the vagina to achieve this purpose. Two of the commonly used antiseptic soaps are povidone iodine and chlorhexidine gluconate. Chlorhexidine gluconate is used for cleansing of the vagina "off-label," meaning that it is not one of the formal uses on the soap's package labelling as approved by the Food and Drug Administration (FDA).

The American College of Obstetricians and Gynecologists endorses both of these different kinds of soaps, currently either because of the surgeon's preference for either soap, or because of a patient's allergy to one of the types of soap.

We think that both soaps will be about the same.

You are being asked to participate in this study because you have a urogynecological condition which requires surgery for treatment, and this surgery will involve a vaginal skin preparation prior to surgery. We hope at least 200 people will take part in this study at the University of New Mexico (UNM).

This form will explain the research study, and will also explain the possible risks as well as the possible benefits to you. We encourage you to talk with your family and friends before you decide to take part in this research study. If you have any questions, please ask one of the study investigators.

What will happen if I decide to participate?

If you agree to participate, you will be assigned by chance (like a flip of a coin) to receive either:

1. An Iodine based soap called "Povidone Iodine" **Or**

2. A different type of soap called "Chlorhexidine Gluconate"

If you agree to participate, you will also complete questionnaires that tell us about your demographic information and medical history. You may refuse to answer any questions at any time. These questions will take about 20 minutes to complete.

You will otherwise receive normal post-surgery care with 2 week and 6 week appointments.

If you are unable to come to your normal post-surgery 2 week or 6 week follow up appointments, we may contact you by telephone to ask questions pertaining to the study.

We will collect demographic information from you when you are enrolled, and will review your medical record if we have missing data. Data collected may include your name, date of birth, phone number, and medical record number.

How long will I be in this study?

Participation in this study will be for 6 weeks after your surgery.

What are the risks or side effects of being in this study?

Randomization risks: You will be assigned to a study procedure by chance, and the procedure you receive may prove to be less effective or to have more side effects than the other study procedure(s) or other available treatments.

There are risks of stress, emotional distress, inconvenience and possible loss of privacy and confidentiality associated with participating in a research study. There is a risk of discomfort while completing the questionnaires provided.

There is a risk that you will be allergic to either of the soaps used in the study. If you have an allergic reaction to either of the soaps used in the study, you will be treated with standard medicines and procedures for allergic reactions.

What are the benefits to being in this study?

There may or may not be direct benefit to you from participating in this study. Povidone iodine and chlorhexidine gluconate are both used as primary surgical preparation soaps for the vagina. The results from this study can help other women in the prevention of infection after their surgery.

What other choices do I have if I do not want to be in this study?

You do not have to participate in this study to receive treatment for your condition, which will be standard treatment with the same type of surgery you have previously been counseled about.

How will my information be kept confidential?

We will take measures to protect the security of all your personal information, but we cannot guarantee confidentiality of all study data.

Information contained in your study records is used by study staff. The University of New Mexico Institutional Review Board (IRB) that oversees human subject research and/or other entities may be permitted to access your records. There may be times when we are

required by law to share your information. However, your name will not be used in any published reports about this study.

We will take measures to protect the security of all your personal information, but we cannot guarantee confidentiality of all study data.

Information collected as part of the study will be labeled with a study number; Information (without your name) will be entered into a computer database/locked file cabinet in the Urogynecology Research office. The PI and his associates will have access to your study information as well as research staff. Data will be stored for 5 years, and then will be destroyed.

Medical information created by this study may become part of your hospital medical record. Information that does not become part of your medical record will be stored in your study file.

What are the costs of taking part in this study?

The study involves using comparably priced surgical soaps prior to surgery, and all other care is standard care. There are no "extra" costs in addition to the cost of your normal medical care and surgery.

Will I be paid for taking part in this study?

You will be not be paid for participating in this study.

How will I know if you learn something new that may change my mind about participating?

You will be informed of any significant new findings that become available during the course of the study, such as changes in the risks or benefits resulting from participating in the research or new alternatives to participation that might change your mind about participating. Additionally, a description of this clinical trial will be available on ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Can I stop being in the study once I begin?

Your participation in this study is completely voluntary. You have the right to choose not to participate or to withdraw your participation at any point in this study without affecting your future health care or other services to which you are entitled.

You may also be removed from the study by the study investigators or research staff.

Whom can I call with questions or complaints about this study?

If you have any questions, concerns or complaints at any time about the research study, Peter Jeppson, or his associates will be glad to answer them at 505-967-8428.

If you need to contact someone after business hours or on weekends, please call 505-272-2111 and ask for Urogynecology Fellow on Call.

If you would like to speak with someone other than the research team, you may call the UNMHSC HRPO at (505) 272-1129.

Whom can I call with questions about my rights as a research participant?

If you have questions regarding your rights as a research participant, you may call the UNMHSC Human Research Protections Office (HRPO) at (505) 272-1129. The HRPO is a group of people from UNM and the community who provide independent oversight of safety and ethical issues related to research involving human participants. For more information, you may also access the IRB website at https://hsc.unm.edu/research/hrpo/

HIPAA Authorization for Use of Your Protected Health Information (HIPAA)

As part of this study, we will be collecting health information about you. This information is "protected" because it is identifiable or "linked" to you.

Protected Health Information (PHI)

By signing this Consent Document, you are allowing the investigators and other authorized personnel to use your protected health information for the purposes of this study. This information may include: results of physical exams, medical history, body mass index, number of pregnancies, and medical conditions.

In addition to researchers and staff at UNMHSC and other groups listed in this form, there is a chance that your health information may be shared (re-disclosed) outside of the research study and no longer be protected by federal privacy laws. Examples of this include disclosures for law enforcement, judicial proceeding, health oversight activities and public health measures.

Right to Withdraw Your Authorization

Your authorization for the use of your health information for this study shall not expire unless you cancel this authorization. Your health information will be used as long as it is needed for this study. However, you may withdraw your authorization at any time provided you notify the UNM investigators in writing. To do this, please send a letter notifying them of your withdrawal to:

Dr. Peter Jeppson
Department of OB/GYN
MSC10 5580, 1 University of New Mexico
Albuquerque, NM 87131

Please be aware that the research team will not be required to destroy or retrieve any of your health information that has already been used or shared before your withdrawal is received.

Contact for Future Research

There may be studies in the future that may be of interest to you. If you are interested in hearing more about these research projects we can contact you in the future. The person contacting you would be your physician or a member of the UNM research team.
Please check below to indicate permission regarding contact for future research.

☐ Yes, you may contact me in the future regarding research projects

☐ No, you may not contact me in the future regarding research projects

Consent and Authorization

You are making a decision whether to participate in this study. Your signature below or verbal consent indicates that you read the information provided (or the information was read to you). By signing this Consent Form, or verbalizing consent, you are not waiving any of your legal rights as a research participant.

I have had an opportunity to ask questions and all questions have been answered to my satisfaction. By signing this Consent Form or verbalizing agreement, I agree to participate in this study and give permission for my health information to be used or disclosed as described in this Consent Form. A copy of this Consent Form has been provided to me.

☐ **Verbal Consent -** By completing the questionnaires and participating in the study, you will be agreeing to participate in the above described research study.

Name of Adult Participant (print) _____ Date of Verbal Consent _____

I have explained the research to the participant and answered all of his/her questions. I believe that he/she understands the information in this consent form and freely consents to participate.

Name of Research Team Member _____ Signature of Research Team Member _____ Date ____

Name of Adult Participant (print) _____ Signature of Adult Participant _____ Date _____

I have explained the research to the participant and answered all of his/her questions. I believe that he/she understands the information in this consent form and freely consents to participate.

Name of Research Team Member Victoria Medina Signature of Research Team Member Victoria Medina Date ____