Randomized Trial of Hibiclens vs Benzoyl Peroxide Soap for Surgical Preparation

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UNIVERSITY OF WASHINGTON
CONSENT FORM

RANDOMIZED TRIAL OF HIBICLENS VS BENZOYL PEROXIDE SOAP FOR SURGICAL PREPARATION

Researchers: Principal
Investigator: Frederick A.
Matsen III, MD
University of Washington, Dept. of Orthopaedics
206-543-3690
matsen@uw.edu

Study Coordinator:
Anastasia J. Whitson
University of Washington, Dept. of Orthopaedics
206-437-9695
ShoulderResearch@uw.edu

24-hour Contact Number: *If you need to speak to someone right away, call the UWMC Paging Operator at (206) 598-6190 and ask to speak to the on-call shoulder fellow.*

Researchers' statement

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent." We will give you a copy of this form for your records.

PURPOSE OF THE STUDY

Propionibacteria (Propi) are bacteria often found in failed joint replacement surgeries. While these bacteria are commonly found on normal skin, many doctors think they cause problems that make it hard for a patient to heal after surgery, especially for male patients. Patients having shoulder replacement surgery at UW are typically instructed to wash with Hibiclens, a liquid soap with the active ingredient chlorhexidine gluconate, before arriving at the hospital on the day of surgery. The goal of washing your skin with this specialized soap before surgery is to lower the chance that the normal skin bacteria would enter the shoulder wound at the time of surgery. A soap bar with the active ingredient benzoyl peroxide (BPO) is a commonly available over-the-counter treatment for acne. Acne can be caused by the same Propi bacteria that the Hibiclens soap is trying to get rid of. The BPO soap may be used in the same way as the Hibiclens soap to wash your skin at home before surgery. We would like to better understand whether the BPO soap is as or more effective than the Hibiclens soap in lowering the amount of Propi in the skin of patients before a shoulder joint replacement.

STUDY PROCEDURES

If you choose to be in this study, you will be randomized into one of two groups. One group will use the BPO soap and the other group will use the Hibiclens soap to wash their skin the night before and morning of surgery. The group you will be in is decided by chance, like the flip of a coin, once you join this study. You have an equal chance of being placed in either group.

We will supply you with the soap and a washing instruction sheet. The clinic nurse will also discuss the washing instructions with you. These are the same instructions you would get if you did not join the study and were washing with the Hibiclens soap before surgery, as all patients getting shoulder replacement surgery at UW are instructed to do. We may call you a few days before surgery to remind you about using the soap and ask if you have any questions.

During surgery, samples of your bacteria are routinely taken and cultured to learn what bacteria are living in and on your skin. This study will not require that any additional samples to be taken; instead, we will use the results from the samples taken for your clinical treatment.

We may obtain the following information from your medical records at the University of Washington Medical Center, Harborview Medical Center, and/or Northwest Hospital:
Demographics: birthdate, age, gender, race, ethnicity, height, weight, handedness, marital status

Symptoms and clinical history: medical and surgical history, clinical family history, allergies, medications, diagnoses, culture results, any X-rays or radiographic images and treatments

RISKS, STRESS, OR DISCOMFORT

We expect the risk of side effects of both soaps to be low. There is a risk of discomfort or irritation from the active ingredients in either of the soaps, including possible redness, burning, itching, peeling, or possibly swelling. Risks will be reduced by asking you in advance if you are sensitive to those ingredients; if so, you will not be eligible to participate in this study. The risks between the two soaps are very similar.

In the event that you experience severe irritation, you should contact us at the 24-hour number listed at the top of this consent form.

There is a risk of hair, towels, or clothing being bleached if they make contact with the soap.

There is a risk that the soap could make your skin sensitive to irritation from the sun. To minimize this risk, avoid spending time in the sun before surgery.

Infection of the shoulder after surgery can happen when bacteria, like Propi, enter the joint and remain there, causing problems of pain, stiffness and loosening of the joint replacement. There is the same amount of risk for infection after surgery whether you use the BPO soap or the Hibiclens soap. If you join this study, you will receive the same care to help lower the risk of infection at the time of surgery as you would if you did not join.

There is a potential risk of loss of confidentiality by participating in this research study. Every effort will be made to keep information confidential; however, this cannot be guaranteed. Information in your medical record will be used for research purposes, and the study team will have access to this information. Some people do not want information from their medical records used for research. If you feel this way, you should not be in this study. More information on confidentiality and privacy is provided below.

ALTERNATIVES TO TAKING PART IN THIS STUDY

If you do not choose to participate in this study, you will not be assigned to one soap randomly. You will be given the soap currently used for surgical preparation, which is Hibiclens, in accordance with our clinical practice.

BENEFITS OF THE STUDY

You will not benefit directly from taking part in this study. We hope that the results of this research will benefit society at large by contributing to prevention of surgical infections and associated complications in the future. If you decide not to participate in this study, you will still receive soap at your pre-operative appointment free of charge.

SOURCE OF FUNDING

There is no external funding or support for this research.

CONFIDENTIALITY OF RESEARCH INFORMATION

The link between your identifiers and the research data will be destroyed after the records retention period required by state and/or federal law.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

OTHER INFORMATION

You may refuse to participate, and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled.

RESEARCH-RELATED INJURY

If you think you have a medical problem or illness related to this research, contact Dr. Frederick Matsen at (206) 543-3690 right away. He will treat you or refer you for treatment.

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098 or call collect at (206) 221-5940. I give permission to the researchers to use my medical records as described in this consent form. I will receive a copy of this consent form.

Printed name of subject	Signature of subject	Date

Copies to: Researcher
Subject