Preadmission Skin Wipe Use for Surgical Site Infection Prophylaxis in Adult Orthopaedic Surgery Patients

NCT03401749
Last updated 2/23/18

A prospective observational cohort study

Contributing Authors:

Eva Lehtonen[1]
Orthopaedic Research Fellow

Sam Huntley[1]
Medical Student

Andrew Moon[1]
Medical Student

Sameer Naranje[1]
Joint Surgeon, Department of Orthopaedics

Gerald McGwin, PhD[1,2],
Statistician

Ashish Shah, MD[1], (ashishshah@uabmc.edu)
Foot and Ankle Surgeon, Primary Investigator

[1]Department of Orthopaedic Surgery, University of Alabama at Birmingham; Birmingham, AL

[2]Department of Epidemiology, University of Alabama at Birmingham; Birmingham, AL

Corresponding Author:
Ashish Shah, M.D.
Associate Professor, Director of Clinical Research
Department of Orthopaedic Surgery
1313 13th Street South, Suite 226
Birmingham, AL 35205

CONSENT FORM

TITLE OF RESEARCH: Efficacy of Preadmission Theraworx™ Wipe Use for Skin Decolonization and Surgical Site Infection Prophylaxis in Adult Orthopedic Surgery Patients: A Randomized Controlled Trial

IRB PROTOCOL NO.: IRB-300000508

PRINCIPAL INVESTIGATOR: Ashish Shah, M.D.

Purpose of the Research

We are asking you to take part in a research study. This research study will test how the addition of Theraworx™ wipes or Chlorhexidine Gluconate (CHG) wipes to our standard pre- operative skin preparation effect the colonization rate of many bacteria. These bacteria are among the most common causes of surgical site infections after orthopedic surgeries. This study will also test how the addition of Theraworx™ wipes or Chlorhexidine Gluconate (CHG) wipes effects the rate of surgical site infections. We will instruct you how to use the wipes and provide you the wipes to use at home the evening before surgery. We will also provide and administer the wipes on the site of the surgery before the procedure begins. There is literature supporting that the use of Theraworx™ or CHG wipes lowers the rate of skin colonization. This is a randomized prospective study and will enroll 500 participants; all of them will come from UAB orthopaedic clinics.

Explanation of Procedures

If you enter the study, you will be placed in one of three groups:

1. One group will receive a standard skin preparation before your surgery. This group is the control group and will undergo orthopedic surgery following UAB's standard guidelines.
2. Another group will be given 2% Chlorhexidine Gluconate (CHG) wipes to take home during your last visit before the surgery. You will be given thorough instructions on how to administer the wipes the night before the surgery. Then, a nurse will use the wipe on you one hour before your standard pre-operative skin preparation on the day of the surgery.
3. The last group will be given Theraworx™ wipes to take home during your last visit before the surgery. You will be given thorough instructions on how to administer the wipes the night before the surgery. Then, a nurse will use the wipe on you one hour before your standard pre-operative skin preparation on the day of the surgery.

Risks and Discomforts

There may be a small chance of breach of confidentiality as a result of electronic information being hacked or stolen. You will be assigned to a group by chance, which may prove to be less effective or to have more side effects than the other study group or alternatives. Some patients may experience mild skin irritation or redness on the application site. Up to 10% may experience dryness, itching, or rash on the application site. Very rarely (less than 1% of patients), patients may experience a serious allergic reaction within minutes after the application of the wipe. Please inform your treatment team if you have ever experienced an allergic reaction to CHG or any other skin product. Symptoms of severe allergic reaction include wheezing or difficulty breathing; swelling of the face; hives that can quickly progress to more serious symptoms; severe body rash; or shock, which is a life-threatening condition that occurs when the body is not getting enough blood flow. If you experience these symptoms seek medical attention immediately.

Benefits

If you are in the group not receiving the topical wipe, you may not directly benefit from taking part in this study. However, this study may help us better understand how to decrease the positive colonization rate in the general population undergoing similar surgeries and maybe decrease post-surgical complications caused by bacterium. This study may also help raise the awareness for future investigations and possibly provide an updated option on standard skin preparation for orthopaedic surgeries.

Alternatives

Your alternative is not to participate in the study.

Confidentiality

Information obtained about you for this study will be kept confidential to the extent allowed by law. However, research information that identifies you may be shared with the UAB Institutional Review Board (IRB) and others who are responsible for ensuring compliance with laws and regulations related to research, including people on behalf of Dr. Ashish Shah and the Office for Human Research Protections (OHRP). The information from the research may be published for scientific purposes; however, your identity will not be given out. This consent document will be placed in your file at UAB Hospital facility. The document will become part of your medical record chart.

Your consent form will be placed in your medical record at UAB Health System or Children's of Alabama. This may include either a paper medical record or electronic medical record (EMR). An EMR is an electronic version of a paper medical record of your care within this health

system. Your EMR may indicate that you are on a clinical trial and provide the name and contact information for the principal investigator.

If you are receiving care or have received care within this health system (outpatient or inpatient) and are participating in a research study, results of research tests or procedures (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing medical record.

If you have never received care within this health system (outpatient or inpatient) and are participating in a research study, a medical record will be created for you to maintain results of research tests or procedures.

Results of research tests or procedures may be placed in your medical record. All information within your medical record can be viewed by individuals authorized to access the record.

A description of this clinical trial will be available on http://www.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.

Voluntary Participation and Withdrawal

Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in the study. If you decide not to be in the study, you will not lose any benefits you are otherwise owed. You are free to withdraw from this research study at any time. Your choice to leave the study will not affect your relationship with this institution.

You may be removed from the study without your consent if the sponsor ends the study, if the study doctor decides it is not in the best interest of your health, or if you are not following the study rules.

If you are a UAB student or employee, taking part in this research is not a part of your UAB class work or duties. You can refuse to enroll, or withdraw after enrolling at any time before the study is over, with no effect on your class standing, grades, or job at UAB. You will not be offered or receive any special consideration if you take part in this research.

Cost of Participation

There will be no cost to you for taking part in this study. The costs of your standard medical care will be billed to you and/or your insurance company in the usual manner.

Payment for Participation in Research

You will not be paid for taking part in this study.

Payment for Research-Related Injuries

UAB has not provided for any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

Questions

If you have any questions, concerns, or complaints about the research or a research-related injury including available treatments, you may contact Dr. Ashish Shah. He will be glad to answer any of your questions. Dr. Shah's number is 205-930-6722.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday. You may also call this number in the event the research staff cannot be reached or you wish to talk to someone else.

Legal Rights

You are not waiving any of your legal rights by signing this informed consent document.

Signatures

Your signature below indicates that you have read (or been read) the information provided above and agree to participate in this study. You will receive a copy of this signed consent form.

Signature of Participant Date

Signature of Principal Investigator or Person Obtaining Consent Date

University of Alabama at Birmingham
AUTHORIZATION FOR USE/DISCLOSURE OF
PROTECTED HEALTH INFORMATION (PHI) FOR RESEARCH

Participant Name:_____ **UAB IRB Protocol Number:** IRB-300000508

Research Protocol: Efficacy of Preadmission Theraworx™ Wipe Use for Skin Decolonization and SSI Prophylaxis in Adult Orthopedic Surgery Patients: A Randomized Controlled Trial

Principal Investigator: Ashish Shah, MD

Sponsor: Dept. of Surgery, Division of Orthopaedics

What is the purpose of this form? You are being asked to sign this form so that UAB may use and release your protected health information for research. Participation in research is voluntary. If you choose to participate in the research, you must sign this form so that your protected health information may be used for the research.

Why do the researchers want my protected health information? The researchers want to use your protected health information as part of the research protocol listed above and as described to you in the informed consent.

What protected health information do the researchers want to use? All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of whatever kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills, and any other information related to or collected for use in the research protocol, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes.

Who will disclose, use and/or receive my protected health information? All Individuals/entities listed in the informed consent documents, including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere); other operating units of UAB, HSF, UAB Highlands, Children's of Alabama, Eye Foundation Hospital, and the Jefferson County Department of Health, as necessary for their operations; the IRB and its staff; the sponsor of the research and its employees and agents, including any CRO; and any outside regulatory agencies, such as the Food and Drug Administration, providing oversight or performing other legal and/or regulatory functions for which access to participant information is required.

How will my protected health information be protected once it is given to others? Your protected health information that is given to the study sponsor will remain private to the extent possible, even though the study sponsor is not required to follow the federal privacy laws. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

How long will this Authorization last? Your authorization for the uses and disclosures described in this Authorization does not have an expiration date.

Can I cancel this Authorization? You may cancel this Authorization at any time by notifying the Principal Investigator, in writing, referencing the research protocol and IRB Protocol Number. If you cancel this Authorization, the study doctor and staff will not use any new health information for research. However, researchers may continue to use the protected health information that was provided before you cancelled your authorization.

Can I see my protected health information? You have a right to request to see your protected health information. However, to ensure the scientific integrity of the research, you will not be able to review the research information until after the research protocol has been completed.

Signature of participant:_____ Date: _____

or participant's legally authorized representative:_____ Date: _____

Printed Name of participant's representative: _____

Relationship to the participant: _____