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AS MODIFIED
Jan 22, 2018
WIRB®

RESEARCH SUBJECT INFORMATION AND CONSENT FORM 180106

TITLE:	Tumescent Anesthesia Antibiotic Delivery (TAAD) and SubQKath for Prevention of Surgical Site Infection, Thrombosis and Sepsis.
PROTOCOL NO.:	TAAD WIRB® Protocol #20171606
FDA IND#:	IND# 127921
SPONSOR:	Jeffrey A. Klein, MD, MPH
INVESTIGATOR:	Name Address City, State Zip Country
STUDY-RELATED PHONE NUMBER(S):	Name Number(s) (24-hour number required)

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by 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. [21 CFR 50.25(c)]

You are encouraged to ask questions regarding this research study. This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. If you prefer, you are welcome to have an unsigned copy of this consent form and take all the time you need to read it carefully, and discuss it with family or friends before making your decision. You can underline or highlight any section of this consent form which you find requires more detailed explanation.

SUMMARY

You are being asked to be in a research study. The purpose of this consent form is to help you decide if you want to be in the research study. Please read this consent form carefully. To participate in a research study you must give your "Informed consent", which includes:

- Reading this consent form
- Having the study doctor or study staff explain the research study to you,

- Asking questions about anything that is not clear, and
- Taking home an unsigned copy of this consent form. This gives you time to think about it and to talk to family or friends before you make your decision.

You will receive a signed and dated copy of this consent form for your records, if you agree to participate in this study. You should not join this research study until all of your questions are answered.

Things to know before deciding to take part in a research study:

- The main goal of a research study is to learn things to help patients in the future.
- The main goal of regular medical care is to help each patient.
- No one can promise that a research study will help you.
- Taking part in a research study is entirely voluntary. No one can make you take part.
- If you decide to take part, you can change your mind later on and withdraw from the research study at any time.
- The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.
- Parts of this study may involve standard medical care. Standard care is the treatment normally given for a certain condition or illness.
- After reading the consent form and having a discussion with the research staff, you should know which parts of the study are experimental and which are standard medical care.
- Part or all of your medical records may become part of the research record. If that happens, your medical records may be looked at and/or copied by the sponsor of this study and government agencies or other groups associated with the study.
- Your medical insurance may be billed for any standard medical care you receive during the research study. If your insurance company is billed then it may have access to the research records. Insurance companies may not pay for treatment that is part of a research study.

After reading and discussing the information in this consent form you should know:

- Why this research study is being done;
- What will happen during the research;
- What study drug or study device or study procedures will be used;
- Any possible benefits to you;
- The possible risks to you;
- The other medical procedures, drugs or devices that could be used instead of being in this research study; and
- How problems will be treated during the study and after the study is over.

- If you take part in this research, you will be given a copy of this signed and dated consent form.

INTRODUCTORY INFORMATION AND PURPOSE

You are being asked to participate in this research study because you may have abdominal surgery, cardiovascular surgery, trauma surgery or burn surgery. The purpose of this research project is to compare the benefits of two methods of preventing a post-operative surgical site infection among patients who are at increased risk of surgical site infections:

1) Intravenous Antibiotic Delivery (IVAD) alone or
2) Tumescent Anesthesia Antibiotic Delivery (TAAD) combined with IV Antibiotic Delivery IVAD. The combination of TAAD and IVAD is designated by (TAAD+IVAD).

IVAD is the traditional method of preventing surgical site infections with antibiotics.

TAAD is a newer investigational technique for antibiotic delivery which involves injection of antibiotics in a dilute solution of lidocaine and epinephrine (local anesthesia) directly into the subcutaneous tissue and fat beneath the skin at the site of the proposed surgical incision.

The present research project involves subjects who may be at increased risk of a surgical site infection. This clinical study is designed to scientifically determine if there are any significant differences between IVAD alone compared to TAAD+IVAD with respect to 1) prevention of SSI, 2) prevention of post-operative blood clots in the legs or lungs, 3) prevention of sepsis and 4) decreased need for post-operative pain medications.

Your participation in this research involves receiving antibiotics with or without local anesthesia before surgery. This research also involves post-operative questionnaires and follow-up visits. If you agree to participate in this clinical study, you will have surgery with one of two possible methods of antibiotic delivery.

1) **IV antibiotic delivery** (**IVAD**) only (the current world-wide standard of care).
2) **IV antibiotics** plus **tumescent antibiotic delivery (IVAD+TAAD)** injected under the skin.

One of the above treatments will be randomly assigned to you. You will have an equal chance of being assigned either treatment.

Questionnaires: After surgery, on three separate occasions, you will be asked to answer questions concerning your surgery.

- within 24 to 36 hours after surgery
- at time of discharge from hospital
- 30 – 45 days after surgery

On these occasions, your surgical incision site will be examined.

Your surgeon will answer your questions about your surgery in detail and discuss all of its risks.

This research does not involve experimental drugs or experimental surgical techniques. All surgical techniques and drug dosages used in this study are standard and have been well described in articles published in the journals of profession surgical societies. The surgical technique will not change. Your surgeon will use the same surgical technique with or without the experimental tumescent antibiotic delivery.

The expected duration of subject participation for each individual volunteer, including follow-up visits for evaluation and photographs, is approximately four weeks. It is expected that there will be approximately 330 to 660 individual volunteer subjects and at least 6 or more surgical centers involved in this research project.

If you are considering the possibility of becoming a volunteer subject, it is appropriate for you to ask any and all questions which you may have. If you are scheduled for elective surgery, you can take this consent form home for consideration before making your final decision about participating in this research study. If your surgery is urgent then you should only decide to participate after careful consideration and getting answers to all of your questions.

Requirements for **Participation:** There are certain requirements for participation in this study. These include:

- You must not be pregnant. If you are a female, you may be required to have a urine pregnancy test on the day of surgery. The urine pregnancy test must be negative.
- You must not have a skin infection at the time of surgery.
- You must agree to discontinue any oral medication which may interfere with a safe use of the local anesthetic drug known as lidocaine. For example, medications containing ketoconazole (Nizoral®), fluconazole (Diflucan®), sertraline (Zoloft®), erythromycin or clarithromycin (Biaxin®) and related drugs may interfere with the metabolism and removal of the local anesthetic lidocaine from the body.

Risks and Discomforts

There may be risks of participation. Some risks of side effects are still unknown. Surgery and the medications used for surgery may be harmful to a fetus and therefore pregnant women are excluded from this study. If you suspect that you have become pregnant, you must notify the study doctor immediately.

There is some difference between the risks or discomfort associated with IVAD and TAAD, the two methods of antibiotic delivery to be used in the present research. There is some discomfort when an IV line is placed in a vein. There is some discomfort when the TAAD solution is infiltrated into the subcutaneous tissue and fat below the skin in the area of where the incision will be made. The degree of discomfort associated with IVAD or with TAAD are approximately the same. The TAAD solution contains a local anesthetic intended to decrease the degree and duration of post-operative surgical pain.

Risk of Antibiotics: your surgeon will choose one or more antibiotics to be given to you to prevent surgical site infection. Your surgeon will explain the risk and benefits of antibiotics to prevent an infection. Among the most commonly used antibiotics are cefazolin and metronidazole. Tell your surgeon if you have any allergy to antibiotics. Antibiotics can cause

Mild upset stomach
Abdominal cramps
Severe watery diarrhea
Vomiting
Allergic reactions including hives, shortness of breath
Swelling of the lips, face or tongue
Fainting
Vaginal itching or discharge

Also, there are risks associated with not using antibiotics

In the case of lidocaine and epinephrine, which are used for tumescent local anesthesia, these side effects, which are very uncommon, include:

Lidocaine injection may cause mild side effects:

Upset stomach
Numbness
Tingling
Drowsiness
Lightheadedness
Dizziness or spinning sensation
Ringing in ears
Difficulty thinking or concentrating
Nervousness or restlessness
Muscle Twitching that you cannot control

Some side effects can be serious. The following symptoms are uncommon, but if you experience any of them, call your study doctor immediately:

Difficulty breathing
Pounding, fast, or irregular heartbeat
Convulsions or seizures
Allergic reactions (itching, hives, swelling) are extremely rare.
Lidocaine injection may cause other side effects.
Some of these reactions could be life-threatening or fatal.

Epinephrine injection may cause side effects:

Upset stomach
Vomiting
Pale skin
Blood pressure too high or too low
Sweating
Dizziness
Nervousness
Weakness
Headache
Shaky hands that you cannot control
Some side effects of epinephrine can be serious. The following symptoms are uncommon, but if you experience any of them, call your study doctor immediately:

Difficulty breathing
Pounding, fast, or irregular heartbeat.
Epinephrine injection may cause other side effects.

Additional Optional Medications may be recommended by your surgeon or anesthesiologist. These drugs are not part of this research study. Your surgeon will discuss and answer your questions regarding these additional medications.

Risks of Infection: There is a risk of infection with any surgical procedure. If you experience any of the following symptoms, call your study doctor immediately:

Fever
Signs of infection on the skin at or near the incision
Signs of infection or increasingly severe pain deep within the surgical
Falling blood pressure
Dizziness or light-headedness
Skin rash or peeling
Unusual bleeding or bruising

Expected Benefits: There is no guarantee that you will receive any medical benefits from being in this study. What we learn in this study may help other surgical patients in the future.

Costs: There will be no extra costs to you or to your insurance company associated with participation in this research project. There will be at least 3 post-operative follow-up examinations and/or follow-up questionnaires. There are no extra charges or fees associated with these examinations or questionnaires. Each of these follow-up encounters will require approximately one hour of your time in addition to the time required for travel to the examinations. Occasionally your follow-up encounter and questionnaire can be conducted by

telephone. These research examinations and questionnaires maybe combined with your routine post-operative follow-up examinations, thus saving you extra travel time.

You might have unexpected expenses from being in this study. Ask your study doctor to discuss the costs that will or will not be covered by the sponsor. This discussion should include who will pay the costs of treating possible side effects.

Payment for Participation: You will not be paid for your participation in this study.

Voluntary withdrawal from this research study: There is no penalty for your withdrawal from this research study. If, for any reason, you are removed from the study by the surgeon or if you decide to withdraw from the study after surgery but before completing the entire study, you will continue to receive the same care and attention as those patients who continue in the study.

Alternative Procedures:

You do not have to participate in this study to have surgery. You may choose to have intravenous antibiotics (IVAD) without participating in this study.

Confidentiality of Records and Information Identifying Research Subjects

Information from this study will be maintained and kept in confidence by your surgeon and his/her study staff. Your surgeon and his/her staff will not share research information about you with anyone during and after the study, except where required by law.

Medical records which identify you and the consent form signed by you will be looked at and/or copied for research or regulatory purposes by your surgeon and may be looked at and/or copied for research or regulatory purposes by:

- Department of Health and Human Services (DHHS) agencies in the United States
- Governmental agencies in other countries; and
- Institutional Review Boards (IRBs)

Absolute confidentiality cannot be guaranteed because of the need to give information to these parties. The results of this research study may be presented at meetings or in publications. Your identity will not be disclosed in those presentations.

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?
The study doctor will get your personal and medical information. For example:

- Past and present medical records

- Research records including photographs
- Records about phone calls made as part of this research
- Records about your study visits.

Who may use and give out information about you?
The study doctor and the study staff.

Who might get this information?
The sponsor of this research. "Sponsor" means any persons or companies that are:
- working for or with the sponsor, or
- owned by the sponsor.

Your information <u>may</u> be given to:
- Department of Health and Human Services (DHHS) agencies within the United States,
- Food and Drug Administration (FDA)
- Governmental agencies in other countries, and
- Western Institutional Review Board® (WIRB®)

Why will this information be used and/or given to others?
- to do the research,
- to study the results, and
- to make sure that the research was done right.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?
Yes, but this permission will not stop automatically. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by providing written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
There is a risk that your information will be given to others without your permission.

Compensation for Injury: In the event of complications associated with this research study, contact your study doctor who treat you or refer you for treatment. You will be billed fees charged by other physicians or hospitals. Your health insurance company may or may not pay for treatment of injuries as a result of your participation in this study.

Source of Funding: The fees for your surgery will be the same whether or not you participate in this antibiotic research project.

The sponsor of this clinical research study, Jeffrey A. Klein, M.D., is helping to finance this research study by paying for the initial data analysis (test) and statistical consultation services provided by the UCR Statistical Collaboratory, University of California, Riverside. Additional funding may include support provided by government research grants.

Each individual hospital is responsible for all of its own expenses which are incurred while participating in this research study. Each individual participating hospital is responsible for covering the cost of the antibiotics and local anesthetics and gathering the data for this research study.

HK Surgical, Inc. (hksurgical.com) is helping this clinical study by providing equipment and supplies for the TAAD procedure "at or below cost" to the hospital.

Additional outside corporate or government funding for this research study may be obtained. Notice of any new or additional financial support will be given within 7 days to you, your surgeon, the hospital, the IRB and all other participants in this research project.

Questions

If you have questions about your participation in this study or in case of injury or complications, or if you have questions, concerns, or complaints about the research, or if further information is desired, contact your surgeon at [phone number (24-hour number required)].

In addition, you may contact the sponsor for this study: Dr. Jeffrey A. Klein, 30280 Rancho Viejo Road, San Juan Capistrano, California 92675

Office Telephone:	949-248-1632
Office Fax:	949-248-9339
Cell Telephone:	949-283-1070
E-mail:	jeff@kleinmd.com

If you have questions about your rights as a research subject or if you have questions, concerns, or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com.

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

Voluntary Participation and Withdrawal: Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled. If you decide to end participation in the research study at any time, your surgeon will continue to provide the same routine follow-up care that is provided to all of his/her patients following surgery.

Your participation in this research study may be ended by your surgeon or the sponsor at any time, without your consent, for any of the following reasons:

- It is in your best interest.
- You do not consent to continue in the study after being told of changes in the research that may affect you.
- Your continued participation is unsafe.
- Your expectations are unrealistic.
- In the surgeon's opinion, it would be unethical to continue.
- Or for any other reason.

New Findings: If there is any new information that might change your decision to be in this study, the study doctor will provide such information to you. You may be asked to sign a revised consent form if this occurs.

Consent: I have read the information in this consent form. My surgeon and the study staff have explained the nature, purpose, possible alternative methods of this research study, the risks involved, and possible complications associated with local anesthesia and surgery. All my questions about the study and my participation in it have been answered. No guarantee has been made as to the results. I freely consent to participate in this research study.

I authorize the use and disclosure of my health information and hospital records to the parties listed in the authorization section of this consent for the research purposes described above.

Time of the Pre-Operative Examination:
To Be Signed at the Time of the Pre-Operative Examination: By signing this consent form, I have not given up any of my legal rights.

Printed Name of Subject:_____

_____
Subject's Signature Date

_____
Witness' Signature Date

_____
Signature of Person Conducting Informed Consent Discussion Date

Print Name(s) of Surgeon(s):_____

_____
Signature of Surgeon(s) Date

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: Tumescent Anesthesia Antibiotic Delivery (TAAD) and SubQKath for Prevention of Surgical Site Infection, Thrombosis and Sepsis.

Day of Surgery
To Be Signed on the Day of Surgery

Subject's Signature (To be signed on date of surgery) Date

Surgery Date/Time Signed

Witness Signature Date

Subject's Telephone # on the Night of Surgery