Lourdes Medical Associates

INFORMED CONSENT TO PARTICIPATE IN RESEARCH

TITLE: A Single Blinded Randomized Control Trial Comparing the Use of ARISTA Polysaccharide Hemostat in Total Knee Arthroplasty (TKA)

INVESTIGATOR: Sean McMillan, DO

SITE(S): Virtua Memorial Hospital, Mt. Holly, NJ

STUDY-RELATED PHONE NUMBER(S): (609) 970-9200

You are being asked to volunteer for a research study conducted by Lourdes Medical Associates. This informed consent form provides you with information that you should know and understand before agreeing to be in this study. After reading this informed consent form, you will be able to ask any questions that you may have. You may take home an unsigned copy of this informed consent form to think about or discuss with family and friends before making your decision.

A total of 30 subjects will be participating in this study at Virtua Memorial Hospital. There will be a total of 60 subjects between two different centers. This study is being sponsored by C. R. Bard (Charles Russell Bard Inc.). The principle investigator will be compensated during the duration of this study. Dr. McMillan is a paid consultant for C. R. Bard.

Your participation will not involve any additional study visits beyond your normal treatment.

WHY IS THIS STUDY BEING DONE?

You are being asked to participate in the study because investigators want to know if there is a safe way to decrease blood loss at the time of a total knee replacement. The purpose of this study is to determine the efficacy of ARISTA (a safe medication already used during surgery to prevent blood loss) compared to a control group of patients not receiving ARISTA. ARISTA is a powdered drug that some doctors use to reduce bleeding during and at the end of surgery. ARISTA has no published data for joint outcomes, however many surgeons use ARISTA in both total knee, hip and shoulder replacements. It works by helping the blood clot quicker and more efficiently.

WHAT WILL YOU BE REQUIRED TO DO?

If you decide to be in this study, the following routine procedures will be performed (the description below includes the scheduled number of visits/procedures:

If you agree to be in this study, then you will be randomized into one of two groups: those receiving ARISTA or those who are not receiving ARISTA. In the first group, ARISTA will be used at the end of surgery to help with bleeding. In the second group, ARISTA will not be used,

but the surgeon will use other methods that are standard of care to help stop bleeding. The chance of being in either group is 50% (or like flipping a coin). You will not know which group you are in, but the investigators will be aware. Before surgery your hemoglobin (which measures how much iron and oxygen are in your blood) will be measured like usual. Also before surgery, your circumference of your thigh will be taken (measures the thickness of your thigh). This measurement will happen again 24 hours after surgery, 14 days after surgery and 3 months after surgery during your post-operative visits with your doctor. Your range of motion will also be measured which is standard of care at 24 hours after surgery, 14 days after surgery and 3 months after surgery during your visits with your doctor. You will also be asked to fill out a short survey before surgery, 24 hours after surgery, 14 days after surgery and 3 months after surgery.

This study will select your treatment by chance. You will be assigned at random to one study group that will not receive ARISTA or one study group that will receive ARISTA. It is not known if any treatment you receive will benefit you.

Your participation will end after your 3 month post operative visit.

ADVERSE EFFECTS

The known dangers, effects, discomforts and foreseeable risks of physical, psychological, sociological, or other harm which you may reasonably expect to occur from being in this study are thromboembolic diseases (i.e. blood clots). The adverse effects listed are pain related to surgery, anemia, nausea, arrhythmia, constipation, respiratory dysfunction, and hypotension.

There may be risks or side effects that are unknown at this time.

Your condition may not get better from being in this study.

PREGNANCY

Women who are pregnant or nursing a child may not participate in this study. You must confirm that, to the best of your knowledge, you are not now pregnant, and that you do not intend to become pregnant during the study.

WHAT BENEFIT CAN YOU EXPECT?

We don't know if this will benefit you but it may lead to decreased blood loss, and/or decreased risk of blood transfusion.

COSTS

The study drug will be supplied free of charge.

You or your insurance company may be billed for:

- Any standard medical care given during this research study.

- The cost of physical therapy is assumed by the patient, however the therapy is not out of the normal for any post knee surgery patient.

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

You may want to talk with your insurance company about its payment policy for standard medical care given during a research study. If your insurance company does not pay, you may be billed for those charges.

If you are injured as a result of your participation in this research project, Lourdes Medical Associates will assist you in obtaining emergency care, if necessary, for your research related injuries. If you have insurance for medical care, your insurance carrier will be billed in the ordinary manner. As with any medical insurance, any costs that are not covered or are in excess of what are paid by your insurance, including deductibles, will be your responsibility. Lourdes Medical Associates' policy is not to provide financial compensation for lost wages, disability pain or discomfort unless required by law to do so. This does not mean that you are giving up any legal rights you may have. You may contact Dr. Sean McMillan, at 609-747-9200 with any questions or to report an injury.

No compensation will be given for participation in this study.

ALTERNATIVES TREATMENTS

You do not have to participate in this study to receive treatment for your condition.

The alternative to being treated with ARISTA to help control bleeding is to use other methods during surgery such as something called thermal ablation (where heat is used to stop bleeding), other powders that form clots to prevent bleeding and intravenous medications used to help stop bleeding.

RELEASE OF PERSONAL INFORMATION

We will do our best to ensure that your personal information is kept confidential and private to the maximum extent required by law. We cannot guarantee absolute confidentially and privacy. Your personal information may be disclosed if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

As part of this research study, you are being asked to release your health information. The Health Insurance Portability and Accountability Act (HIPAA) permits a hospital or doctor's office to use or release protected health information (PHI) for the purposes of treatment, payment of health care operations. A HIPAA authorization gives permission from you to use or release PHI for research purposes, and is in addition to your consent to participate in this research study.

Confidentiality of Study Records and Medical Records

Information collected for this study is confidential. However, the investigator and his/her study staff, delegated representatives of Virtua Health System Institutional Review Board (IRB), the sponsor and/or their representatives, the Food and Drug Administration (FDA) and other government agencies involved in keeping research safe for people may look at your medical records when necessary, either in person, by mail, fax or electronically.

- Data will be stored in a locked filing cabinet.
- People who could have access to your information:
  - Researchers and research staff
  - Institutional Review Board (IRB)
  - Sponsor
  - Government agencies (e.g., FDA).

HIPAA

In working with the sponsor, the investigator Dr. McMillan, will use and share personal health information about you. This is information about your health that may also include your name, address, telephone number or other facts that could identify the health information as yours. This includes information in your medical record and information created or collected during the study. This information may include you medical history, physical exam and laboratory test results. Some of these tests may have been done as part of your regular care. The investigator will use this information about you to complete this research.

In most cases, the investigator will use your initials and assign a code number to your information that is shared with the sponsor. The sponsor and its representative may review or coy your personal health information at the study site. Regulatory authorities and the Lourdes Health System Institutional Review Board may also review or copy you information to make sure that the study is done properly or for other purposes required by law.

By signing this Authorization, you allow the investigator to use your personal health information to carry out and evaluate this study. You also allow the investigator to share your personal health information with:

- The sponsor and its representatives
- The Virtua Health System Regional Institutional Review Board
- The U.S. Food and Drug Administration (FDA)
- Other regulatory agencies, e.g., National Institutes of Health (NIH) and Department of Health and Human Services (DHHS).

Your personal health information may be further shared by the groups above. If shared by them, the information will no longer be covered by the Privacy Rule. However, these groups are committed to keeping your personal health information confidential.

You have the right see and get a copy of your records related to the study for as long as the investigator has this information. However, by signing this Authorization you agree that you

might not be able to review or receive some of your records related to the study until after the study has been completed.

You may choose to withdraw this Authorization at any time, but you must notify the investigator in writing. Send your written withdrawal notice to Dr. Sean McMillan, at 2103 Mt. Holly Road, Burlington, NJ 08016. If you withdraw from the study and withdraw your Authorization, no new information will be collected for study purposes unless the information concerns an adverse event (a bad effect) relate to the study. If an adverse event occurs, your entire medical records may be reviewed. All information that has already been collected for study purposes, and any new information about an adverse event to the study, will be sent to the study sponsor.

If you withdraw from the study but do not withdraw your Authorization, new personal health information may be collected until this study ends.

VOLUNTARY PARTICIPATION/WITHDRAWAL

Your decision to take part in this study is completely voluntary. You are free to choose not to take part in the study and may change your mind and withdraw at any time. Your relationship with physicians at Virtua and your medical care at Virtua, now or in the future, will not be affected in any way if you withdraw or refuse to participate. You will not lose any benefits to which you are otherwise entitled.

The study doctor and/or the sponsor may terminate your participation in this study at any time without your consent if, in their judgment, it is inadvisable for you to continue.

COMPENSATION FOR INJURY

If you are injured as a result of participating in this study, the study doctor, other members of the research team, or other Virtua professional medical staff will provide you with emergency medical treatment (or arrange to have such treatment provided to you), and will assist you in obtaining appropriate follow-up medical treatment. However, there is no plan to routinely provide compensation for additional medical care or other costs.

Your health insurance may or may not pay for treatment of injuries as a result of your participation in this study.

QUESTIONS

If you have any additional questions later on, or if you wish to report a medical problem that may be related to this study, Dr. Sean McMillan can be reached at (609) 747-9200 during office hours and at (609) 747-9200 after business hours.

If you have any questions about your rights as a research subject and/or your participation in this study that you would like to ask an institutional representative who is not part of this study, you can contact the Virtua General Institutional Board (856)761-3844.

If you would like to have more information about the Hospital's financial disclosure review process in general, or in regard to this study, you may contact 609-914-6000

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.

If you decide to be in this study:

- You are expected to follow the study procedures.
- You are expected to provide the information needed by the study doctor, the study coordinator, nurses, or other staff members for the study.
- You will be told in a timely manner of any significant new information that may affect your willingness to stay in the study.
- You may freely choose to stop being in the study at any time.

By signing below, you are voluntarily agreeing to be in this study.

You must be given a signed copy of this informed consent form to keep for yourself.

Print Name of Participant	Signature of Participant	Date

Print Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date

As a Virtua representative, please sign here to indicate that you have given a signed copy of this informed consent form to the participant.

APPROVED
AUG 13 2020
VIRTUA
Institutional Review Board