THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

Randomized Controlled Trial of Repeat vs. Single Quadratus Lumborum Block to Reduce Opioid Prescriptions After Open Resection of Retroperitoneal Sarcoma ("RESQU-SARC" Trial)
2019-0780

Study Chair: Christopher P. Scally

_____ _____
Participant's Name Medical Record Number

This is an informed consent and authorization form for a research study. It includes a summary about the study. A more detailed description of procedures and risks is provided after the summary.

This research has been reviewed and approved by an Institutional Review Board (IRB – an ethics committee that reviews research studies).

STUDY SUMMARY

The goal of this research study is to compare 2 different schedules for providing pain control to retroperitoneal sarcoma patients who are having surgery. Researchers want to learn if one of these schedules may lead to fewer patients needing opioid pain medications at the end of the hospital stay.

This is an investigational study. All medications and numbing medication injection blocks (described below) used in this study are FDA approved and commercially available. It is investigational to compare the different ways of providing pain control. The only thing being studied is comparing the order of getting numbing medication injections.

Receiving a second injection block may decrease dependency on opioid medications for pain relief after surgery and prevent long-term use and addiction. Future patients may benefit from what is learned. There may be no benefits for you in this study.

Your participation is completely voluntary. Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including side effects, potential expenses, and time commitment. You may not want to take part in this study due to the possibility of receiving an injection of numbing medication on Day 4 of the study.

You can read a full list of potential side effects below in the Possible Risks section of this consent.

For this study, you will be asked to complete questionnaires for up to 1 year.

You and/or your insurance provider will be responsible for the costs of surgery, hospitalization, and all drugs you may receive while you are in the hospital.

You do not have to take part in this study to have surgery. Your decision on this study will not impact your surgeon's decision on surgery or the outcome of the actual operation. You will receive appropriate medical care, including treatment for pain and other symptoms related to your surgery.

1. STUDY DETAILS

Up to 106 participants will be enrolled in this study. All will take part at MD Anderson.

If you agree to take part in this study, it will not affect your surgery. All participants will receive standard general anesthesia before and during surgery. This includes the standard injection, or "block" of numbing medication to reduce your total need for opioids. You will then receive the standard of care for post-surgery recovery, which includes non-opioids and opioids.

However, you may also be randomly assigned on Day 3 (as in the flip of a coin) to receive or not receive a second numbing "block" on Day 4 after surgery. You will have an equal chance of receiving the second block or not. You may refuse to have this done if you are already off all opioids and/or are being discharged on or before the morning of Day 4.

As part of the standard of care, you will be asked about your pain every few hours throughout your stay in the hospital.

You will complete a brief questionnaire about your symptoms 2 times while you are in the hospital, then 3 times 1, 3, and 12 months after the surgery. The questionnaires may be given over the phone, email, or in clinic. You will never need to come to the hospital just to complete the questionnaire. It should take about 2 minutes to complete the questionnaire each time. Your participation in this study will be over after you complete the last questionnaire.

2. POSSIBLE RISKS

While on this study, you are at risk for side effects. You should discuss these with the study doctor. The more commonly occurring side effects are listed in this form, as are rare but serious side effects. You may also want to ask about uncommon side effects that have been observed in small numbers of patients but are not listed in this form. Many side effects go away shortly after treatment is stopped, but in some cases side effects may be serious, long-lasting or permanent, and may even result in hospitalization and/or death.

Side effects will vary from person to person, and some may occur after you have stopped receiving treatment. Tell the study staff about any side effects you may have, even if you do not think they are related to the study drug/procedures.

If you receive a **second "block,"** it will have the same risks as the first block that all participants will have received. These include injection site pain, bruising, and/or bleeding. You may have an allergic reaction to the block, but this would already be known due to your just having received the first block several days before. If you had an allergic reaction, the block would not be repeated.

Questionnaires may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns about completing the questionnaire, you are encouraged to contact your doctor or the study chair.

Although every effort will be made to keep study data safe, there is a chance that your personal health information could be lost or stolen, which may result in a **loss of confidentiality**. All study data will be stored in password-protected computers and/or locked file cabinets and will continue to be stored securely after the study. Physical copies of data will be stored in an MD Anderson-approved long-term off-site storage center, and electronic data will be kept indefinitely on MD Anderson services behind an institutional firewall. Your study data and paper records will not be destroyed; they will be kept permanently.

This study may involve unpredictable risks to the participants.

3. COSTS AND COMPENSATION

If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson for this injury. You may also contact the Chair of MD Anderson's IRB at 713-792-6477 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

Certain tests, procedures, and/or drugs that you may receive as part of this study may be without cost to you because they are for research purposes only. However, your insurance provider and/or you may be financially responsible for the cost of

care and treatment of any complications resulting from the research tests, procedures, and/or drugs. Standard medical care that you receive under this research study will be billed to your insurance provider and/or you in the ordinary manner. Before taking part in this study, you may ask about which parts of the research-related care may be provided without charge, which costs your insurance provider may pay for, and which costs may be your responsibility. You may ask that a financial counselor be made available to you to talk about the costs of this study.

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research.

You will receive no compensation for taking part in this study.

Additional Information

4. You may ask the study chair (Dr. Christopher P. Scally, at 713-792-6940) any questions you have about this study. You may also contact the Chair of MD Anderson's Institutional Review Board (IRB - a committee that reviews research studies) at 713-792-6477 with any questions that have to do with this study or your rights as a study participant.

5. You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits. If you decide you want to stop taking part in the study, it is recommended for your safety that you first talk to your doctor. If you withdraw from this study, you can still choose to be treated at MD Anderson.

   If you stop being in the research, already collected data may not be removed from the study database. You may be asked whether the study doctor can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

6. This study or your participation in it may be changed or stopped without your consent at any time by the study chair, the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), or the IRB of MD Anderson.

7. You will be informed of any new findings or information that might affect your willingness to continue taking part in the study, and you may be asked to sign another informed consent and authorization form stating your continued willingness to participate in this study.

8. MD Anderson may benefit from your participation and/or what is learned in this study.

Future Research

Data

Your personal information is being collected as part of this study. These data may be used by researchers at MD Anderson and/or shared with other researchers and/or institutions for use in future research.

You may withdraw your consent to future research at any time. If you do not want your data to be used for future research, tell the study coordinator. However, any data that has already been released and used in research may continue being used, to preserve the scientific integrity of the analysis.

Authorization for Use and Disclosure of Protected Health Information (PHI):

A. During the course of this study, MD Anderson will be collecting and using your PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety-related reasons, your doctor and the research team may share your PHI with:
   - Federal agencies that require reporting of clinical study data (such as the FDA, National Cancer Institute [NCI], and OHRP)
   - The IRB and officials of MD Anderson
   - Study monitors and auditors who verify the accuracy of the information
   - Individuals who put all the study information together in report form

   Study sponsors and/or supporters receive limited amounts of PHI. They may also view additional PHI in study records during the monitoring process. MD Anderson's contracts require sponsors/supporters to protect this information and limit how they may use it.

   The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

B. Signing this consent and authorization form is optional but you cannot take part in this study or receive study-related treatment if you do not agree and sign.

C. MD Anderson will keep your PHI confidential when possible (according to state and federal law). However, in some situations, the FDA could be required to reveal the names of participants.

   Once disclosed outside of MD Anderson, federal privacy laws may no longer protect your PHI.

D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.

E. 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.

CONSENT/AUTHORIZATION

I understand the information in this consent form. I have had a chance to read the consent form for this study or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

_____ _____
SIGNATURE OF PARTICIPANT DATE

_____
PRINTED NAME OF PARTICIPANT

PERSON OBTAINING CONSENT

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

_____ _____
PERSON OBTAINING CONSENT DATE

_____
PRINTED NAME OF PERSON OBTAINING CONSENT