THE EFFECT OF SURGICAL STABILIZATION OF RIB FRACTURES ON CLINICAL AND PATIENT-CENTERED OUTCOMES: A RANDOMIZED CLINICAL TRIAL

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CONSENT TO TAKE PART IN RESEARCH

Simple Study Title: SSRF Trial

Full Study Title: THE EFFECT OF SURGICAL STABILIZATION OF RIB FRACTURES ON CLINICALAND PATIENT-CENTERED OUTCOMES: A RANDOMIZED CLINICAL TRIAL

Study Sponsor: University of Texas Health Science Center - Houston

Principal Investigator: David Meyer, MD, MS, FACS
Assistant Professor Department of Surgery
University of Texas Health Science Center at Houston

Study Contact: Rosemarie Juarez, RN [redacted]

The purpose of this trial is to compare the effectiveness of surgical treatment to those patients who do not have surgical treatment for rib fractures. If you choose to take part in this trial, you will be asked to allow us to randomize you into one of two groups (surgical versus non surgical) and contact you up to 6 months after your injury to ask questions about your quality of life. The total amount of time you will be in this trial is up to 6 months.

There are potential risks involved with this trial that are described in this document. Some known risks related with rib fractures include pain, pneumonia, and respiratory problems. There may be potential benefits to you such as decreased pain and improved clinical outcomes. The only alternative to this trial is to not take part.

Participation in this research trial is voluntary. You may choose not to take part in this research trial or may choose to leave the research trial at any time. Your decision will not affect the clinical care you receive at the University of Texas Health Science Center at Houston (UTHealth), and Memorial Hermann Healthcare System.

If you are interested in participating, please continue to read below.

If you are unable to provide written informed consent, or have legally transferred authority to consent for health care decisions to another person, a Legally Authorized Representative may consent on your behalf to take part in this trial. “You” refers to the patient in this consent form.

What is the purpose of this research study?
The purpose of this trial is to see how well surgical treatment works at treating people with rib fractures. This trial will evaluate two treatments currently used to treat patients with rib fractures at UTHealth and Memorial Hermann Hospital – Texas Medical Center (MHH-TMC). The study will compare the use of surgical stabilization plus usual care to usual care only. The surgical treatment is an approved procedure.

This is a local study will enroll a total of 150 people. UTHealth is paying for this study to be completed.

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. Law. This will not include information that can identify you. After the trial has ended, website will include a summary of the results. You can search this website at any time.

Who is being asked to take part in this study?

You are being asked to take part in this research trial because you have experienced rib fractures from a traumatic injury. This trial is conducted at UTHealth and MHH-TMC. About 150 people will take part in the trial at UTHealth and Memorial Health System.

What will happen if I take part in this study?

It is not known whether the surgical treatment will be of benefit. This trial is looking to see if the surgical treatment improves the overall health status up to 6 months after injury. This will allow us to compare the benefits and side effects of the surgical treatment compared to usual care. If you agree to take part in this study, you will be randomized (similar to flipping a coin) to have surgical treatment plus usual care or usual care alone. There is a 50% chance you will have surgical treatment as part of this trial and a 50% chance that you will receive usual care. You and your doctor will know which group you are randomized to.

During your hospital stay, we will collect data from your medical records regarding your clinical care. We will also contact you at 1, 3, and 6 months after your injury to ask you questions about your quality of life and how you are feeling. This can be done over the phone or in person if you are here for a routine clinic appointment. The questionnaire will take about 10 to 15 minutes to complete.

How long will you be in the study?

If you agree to take part, your participation will last for up to 6 months. You will be contacted at 1, 3, and 6 months following your hospital admission to complete a quality of life questionnaire that will take about 10 to 15 minutes each time.

What choices do you have other than this study?

The only option to this trial is to not take part. You will receive the care that the attending physician feels is best for treating your rib fractures. You will be asked at the time of each questionnaire (1, 3, and 6 months) if you want to complete the questionnaire.

What are the risks of taking part in this study?

There are both risks and benefits to taking part in this trial. The study doctor will discuss these risks with you. This study may include risks that are unknown at this time. It is important for you to think carefully about these as you make your decision.

If you choose to take part in this trial, there is a risk that the surgical treatment may or may not be as good as the usual care in treating your rib fractures.

Some of the most common side effects following rib fractures that the doctors know about are: Pain, pneumonia, increased time on the ventilator and acute respiratory problems. Common complications or problems with the surgical treatment include surgical site infection and possible bleeding at time of surgery. The bleeding occurs at a low rate.

In addition to the common problems following rib fractures, there is also the possibility of breach of confidentiality. All information collected for the purposes of this trial will be de-identified. You will have a trial specific ID number. All information will be kept in a secure locked area and/or on password protected computers.

Questionnaires: You may get tired when we are asking you questions or you are completing questionnaires. You do not have to answer any questions you do not want to answer.

There may be some risks that the study doctors do not yet know about.

What are the benefits to taking part in this study?
There is some evidence in people with rib fractures that surgical treatment can decrease the pain level, decrease amount of time on the ventilator and improve quality of life. However, we do not know if this will happen in everyone with rib fractures. This trial may help the trial doctors learn things that may help other people in the future.

Can you stop taking part in this study?
You may decide to stop taking part in the trial at any time. To withdraw from the trial, please contact Dr. Meyer at [redacted].

Your doctor or the sponsor can stop the trial at any time. Your doctor or the sponsor may stop your participation in the trial if your condition worsens, the trial is stopped, you do not meet all the requirements of the trial, or the trial is not in your best interest. If your participation in the trial is stopped, your doctor will discuss other options for your treatment.

If you stop participating in this trial, the information already collected about you will still be used in the data analysis. However, no further information will be collected without your permission.

While taking part in this trial, the trial team will notify you of new information that may become available and could affect your willingness to stay in the trial.

What happens if you are injured during the study?
In the event of injury resulting from this research, UTHealth and/or Memorial Hermann Health System are not able to offer financial compensation nor to absorb the costs of medical treatment. If you suffer an injury as a result of taking part in this research trial, please understand that nothing has been arranged to provide free treatment of the injury or any other type of payment. However, necessary facilities, emergency treatment, and professional services will be available to you, just as they are to the general community. You or your insurance company will be billed for any treatment. You should report any such injury to Dr. Meyer at [redacted]. You will not give up any of your legal rights by signing this consent form.

What are the costs of taking part in this study?
The sponsor will pay for the special tests and exams that are required by this trial and not otherwise part of your standard medical care. However, many of the tests, procedures, and exams you will receive are believed to be part of standard medical care, and may or may not be covered by your medical insurance. If your medical insurance does not pay for your care you will be responsible for the cost of

the medical care related to your condition including laboratory tests, deductibles, co-payments, physician and clinic fees, hospitalization and procedures.

If you receive a bill that you believe is related to your taking part in this research trial, please contact Dr. Meyer, or research staff at [redacted] with any questions.

Will you be paid for taking part in this study?
You will not receive any compensation for taking part in this study.

The University of Texas Health Science Center at Houston owns any data collected and the use of the data, results, treatments, or inventions that can be made from the research. The University's ownership includes the right to license or transfer the use or ownership to other parties including without limitation, commercial entities contracting with UTHealth. There are no plans to compensate you for any patents or discoveries that may result from your participation in this research study. You will not be paid for any use of your data, samples, or results.

How will privacy and confidentiality be protected?
Your privacy is important and your participation in this trial will be kept confidential. However, absolute confidentiality cannot be guaranteed.

If you sign this document, you give permission to UTHealth and Memorial Hermann Healthcare System to use and disclose (release) your health information. The health information that we may use or disclose for this research includes: prehospital information, vital signs, lab reports, procedure and diagnostic reports, lab results, discharge notes, and physician notes.

Personal identifiers such as your name and medical record number will be removed from the information and samples collected in this trial. After we remove all identifiers, the information or samples may be used for future research or shared with other researchers without your additional informed consent.

People who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect your health information and may share your information with others without your permission, if permitted by laws governing them. You will not be personally identified in any reports or publications that may result from this trial. If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes. Please understand that health information used and disclosed may include information relating to HIV infection, drug abuse, alcohol abuse, behavioral health, and psychiatric care.

Representatives of the organizations listed below will see your name and other personal identifiers when they review your research records and medical records for the purposes of verifying trial data:

- Representatives of UTHealth and/or Memorial Hermann Health System
- Members of Data and Safety Monitoring Boards (an independent group of experts that reviews this trial's data to make sure participants are safe and the research data is reliable)

- Companies engaged with the UTHealth for the commercialization of the results of the research study.

Please note that you do not have to sign this Authorization, but if you do not, you may not take part in this research trial. UTHealth and Memorial Hermann Health System may not withhold treatment or refuse treating you if you do not sign this Authorization.

You may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, researchers may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this Authorization, you must contact Dr. David Meyer in writing at [redacted].

This Authorization will expire 15 years after the end of the trial.

Whom can you contact if you have questions about the study?

If you have questions at any time about this research trial, please feel free to contact the Dr. Meyer or his study coordinator at [redacted], as they will be glad to answer your questions. You can contact the trial team to discuss problems, report injuries, voice concerns, obtain information in addition to asking questions about the research.

The Committee for Protection of Human Subjects at the University of Texas Health Science Center has reviewed this research trial. You may contact them for any questions about your rights as a research subject, and to discuss any concerns, comments, or complaints about taking part in a research trial at [redacted].

SIGNATURES

Sign below only if you understand the information given to you about the research and you choose to take part in this research trial. Make sure that all your questions have been answered. If you decide to take part in this research trial, a copy of this signed consent form will be given to you.

Printed Name of Subject	Signature of Subject	Date	Time
Printed Name of Legally Authorized Representative	Signature of Legally Authorized Representative	Date	Time
Printed Name of Person Obtaining Informed Consent	Signature of Person Obtaining Informed Consent	Date	Time