COMIRB
APPROVED
For Use
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Principal Investigator: Fredric M. Pieracci, MD, MPH
COMIRB No: 17-1432
Clinical Trial Number: NCT03221595
Version Date: 4/2/2019 OBSERVATIONAL

Study Title: A Multicenter, Randomized Controlled Trial of Surgical Stabilization of Rib Fractures in Patients with Severe, Non-flail Fracture Patterns (CWIS NON FLAIL)

OBSERVATIONAL

You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

This study plans to learn more about treatment options for patients with severe rib fractures. Specifically, we are investigating if placing thin, permanent plates on the fractures to stabilize them will improve pain control and quality of life.

You are being asked to be in this research study because you have been hospitalized with three or more severely displaced (broken) rib fractures, and your pain and breathing are affected because of your fractures.

You are also being asked to be in the "observational" arm of this research study because you declined to participate in the "randomized" arm of the study.

We are conducting this study because there is no clear best treatment for patients with rib fractures like yours. Some surgeons believe that surgery is beneficial, whereas other do not. Performing this study will allow surgeons to better understand the best way to treat patients with rib fractures like yours.

Other people in this study

Up to 100 people from your area will participate in the study. Up to 100 people around the country will be in the study.

What happens if I join this study?

You have already declined to participate in our randomized trial. Accordingly, whether or not you receive surgery for your rib fractures will be decided by you and your treatment team. The purpose of this consent is to give the researchers permission to collect information about your rib fracture treatment, whatever that may be. Again, by consenting to this study, you are *not* agreeing to be randomized to a particular treatment of your rib fractures. Rather, your treatment will be determined by you and your treatment team. You are simply allowing the research to collect information about how your treatment is going, such as requirements for pain medicine, breathing ability, and quality of life.

If you agree to allow the researchers to collect data on your rib fractures, you will still receive all of the standard treatments for your rib fractures that you would receive if you were not in this trial.

When you see us in clinic two weeks after your discharge, you will also undergo a noninvasive breathing test, which lasts about 30 minutes, called pulmonary function tests. This test will be paid for by the study and coordinated with your clinic visit so that you do not have to come back a second time. You will also complete a 1 page questionnaire about your rib fractures at every follow-up visit.

Participation in this study will last for up to two months.

What are the possible discomforts or risks?

Since we are only collecting data on how your rib fracture treatment is going, there are no discomforts or risks to the study.

We will do all that we can to protect your information, but there is always a small risk that people outside of the research team will see your research information.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about surgery to treat rib fractures. This study is not designed to treat any illness or to improve your health. Also there may be risks, as discussed in the section describing the discomforts or risks.

Initials_____

Who is paying for this study?

This research is being sponsored by DePuy, Synthes, Inc., the manufacturer of one of the rib fixation systems that may be used in this trial.

The study doctor, Dr. Pieracci, is a paid educator for DePuy Synthes, and receives income from them to teach other surgeons the technique of rib fixation at national courses. The Chest Wall Injury Society (CWIS) is the sponsoring Society of this study. Dr. Pieracci is currently the president of The Chest Wall Injury Society. CWIS provides non-financial resources for the trial. Please feel free to ask any questions you may have about this matter. Already enrolled subjects from all study sites are notified about Dr. Pieracci's relationship with De-Puy Synthesis and Chest Wall Injury Society.

Will I be paid for being in the study?

You will not be paid to be in the study.

Will I have to pay for anything?

It will not cost you anything to be in the study; your insurance will be billed for all standard medical care while you participate in this study. You may want to talk to your insurance company about its payment policy for standard medical care given during a study.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

If you leave this study, you will still receive your normal medical care. The only medical care that you will lose is the medical care you are getting as part of this study. You might be able to get that same kind of medical care outside of the study. Ask your study doctor.

Can I be removed from this study?

The study doctor may decide to stop your participation without your permission if the study doctor thinks that being in the study may cause you harm, or for any other reason.

Initials_____

What happens if I am injured or hurt during the study?

Every effort to prevent any injury resulting from this study will be taken by Dr. Pieracci and the research team. If you have an injury while you are in this study, you should immediately call Dr. Pieracci at 303-436-4029 We will arrange to get you medical care if you have an injury that is caused by this research. However, you or your insurance company will have to pay for that care.

Who do I call if I have questions?

The researcher carrying out this study is Dr. Pieracci. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Dr. Pieracci at 303-436-4029 or the study research coordinator, Kiara Leasia, MD at 303-602- 6213. You will be given a copy of this form to keep.

You may have questions about your rights as someone in this study. You can call Dr. Pieracci with questions. You can also call the responsible Institutional Review Board (COMIRB). You can call them at 303-724-1055.

Who will see my research information?

The University of Colorado Denver (UCD) and its affiliated hospital(s) have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include Denver Health

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the UCD and its affiliate hospitals may not be covered by this obligation.

We will do everything we can to maintain the confidentiality of your personal information but confidentiality cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Principal Investigator (PI), at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Fredric M. Pieracci, MD, MPH
Denver Health Medical Center
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Denver, CO 80204

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information, such as:.

- Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The study doctor and the rest of the study team.
- DePuy, Synthes Inc., who is the company paying for this research study.
- Fireflylabs LLC and Healthcare Blocks, which are the computer entities that securely store your personal information for the study researcher to analyze.
- Officials at the institution where the research is conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

You have the right to request access to your personal health information from the Investigator.

Information about you that will be seen, collected, used and disclosed in this study:

- Demographic Information: age and gender
- Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, procedure results
- Research Visit and Research Testrecords

Initials_____

Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature:_____ Date:_____

Print Name:_____

Consent form explained by:_____ Date:_____

Print Name: _____

Witness Print Name:_____

Signature:_____Date:_____

Witness of consent process:_____Date_____