RESEARCH CONSENT/AUTHORIZATION FORM
IRB # 2018-0533

STUDY TITLE: Glucocorticoid Administration in the Treatment of Adult Distal Radius Fractures: A Randomized Controlled Trial
PRINCIPAL INVESTIGATOR: C. Liam Dwyer, MD
SITE(S): Geisinger Clinic, 100 N. Academy Ave, Danville, PA 17822-2130
PHONE NUMBER: 570-271-6541
24-HOUR PHONE NUMBER: 570-271-6211 (Hospital Switchboard)

You are being asked to participate in this research study because you have a DISTAL RADIUS FRACTURE and have decided to treat the fracture with surgery. This is also known as a wrist fracture, which is a broken bone in your arm. The goal of this study is to find if there is a difference in function and motion after treatment of this injury when using glucocorticoids (also known as “steroids”). This will be compared to not using steroids. As of now, it is not known if steroids can help with this injury. Steroids can be helpful for treating some types of fractures and broken bones in the elbow.

WHY IS THIS STUDY BEING DONE?
The Orthopaedic Surgery department hopes this study will help to better understand if steroids can be used to improve function after wrist fractures. We are comparing patients who receive steroids to those who do not.

WHO WILL BE IN THE STUDY?
Around 200 subjects at Geisinger Medical Center will be involved in this study.

WHAT WILL I BE ASKED TO DO?
If you choose to participate, you will be randomized into one of two groups. This means that a random number from a computer program will place you into one of two groups: patients receiving steroids or patients not receiving steroids. Subjects in the steroid group will be given a single dose of intravenous steroids during surgery and a 6-day oral steroid taper. This means that if you are enrolled in the steroid group, you will be asked to take pills every day for 6 days after the surgery.

After the surgery, you will be asked to come in to clinic for follow-up appointments, just as you would if you were not participating in the study. These appointments will take place at 2 weeks, 6 weeks, 3 months, 6 months, and 1 year after the surgery. At these visits, you will fill out questionnaires as part of your regular clinic visits. No extra paperwork will need to be completed for this study. These questionnaires are:

1. VAS Pain
2. PROMIS Upper Extremity – Short Form 7a
3. QuickDASH

The assessments and surveys will take about 10 to 15 minutes for each session. As part of your routine care, you will also have occupational therapy sessions and wrist X-rays to track your progress.

HOW LONG WILL I BE IN THE STUDY?
You will be in the research study for about 1 year after surgery. You will only need to attend your regularly scheduled clinic appointments. No extra visits are necessary.

WHAT ARE THE RISKS OF THE STUDY?
There are some risks related to steroids, but most of these are related to long-term use. The short-term usage of steroids is usually safe. These medications are commonly used in surgery to help with nausea after surgery, pain and swelling. They are also used to treat inflammation related to injuries or trauma.

Side effects include increased blood sugar levels, changes in appetite, changes in mood, dizziness, trouble sleeping, and allergic reactions. You will not be asked to participate in the study if you have certain medical conditions that prevent the usage of steroids.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
There will be no direct benefit to you if you choose to participate in this study. The investigators hope the information from this study will provide a better understanding of how to best improve motion and function after wrist fractures.

WHAT OTHER OPTIONS ARE THERE?
You may choose not to participate in this study without any impact on your care at Geisinger.

WHAT ABOUT CONFIDENTIALITY?
Efforts will be made to keep your personal information private. Any personal data will be stored behind locked doors in the research team office or on password-protected computers. Your personal data may be released if required by law. Federal Privacy Regulations provide precautions for privacy, security, and authorized access.

The study results will be retained in your research record indefinitely and could be used for future research.

If data or information from the research study is submitted for publication in a medical journal or is presented at a medical meeting, your identity will not be revealed.

WHAT ARE THE COSTS?

For this study, we will collect information about you and your medical care.
You will not have any additional costs because of participating in this study. You or your insurance will be billed for the routine care that you are provided. This routine care includes:

- the surgical procedure
- prescribed medications
- clinic visits (pre-surgery, 2 weeks post-surgery, 3 months post-surgery, 6 weeks post-surgery, 6 months post-surgery, and 1 year post-surgery).

You will be responsible for any co-pays or cost-sharing that comes from your routine care, as determined by your insurance provider.

You will not be compensated for participating in this study.

WHAT HAPPENS IF I AM HURT WHILE I AM IN THE STUDY?

In the case of injury or illness resulting from this research study, medical treatment is available. It will be provided at the usual charge. Immediately contact the study doctor, C. Liam Dwyer, MD at 570-271-6541.

You or your insurance company will also be charged for continuing medical care and/or hospitalization required for any such injury or illness. Your health insurance company may or may not pay for treatment of injuries because of your participation in this study.

No funds have been set aside to compensate you in the event of injury or illness.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this research study is voluntary. You may choose not to be in the study. You may also withdraw from the study at any time. You may also withdraw your permission for us to use your data. Data that has already been collected cannot be withdrawn.

Your decision not to join or to withdraw from the study will not involve any penalty or loss of benefits. If you do decide to withdraw, we ask that you contact the principal investigator. This must be done in writing, stating that you are withdrawing from the study.

Please contact:
C. Liam Dwyer, MD
Department of Orthopaedic Surgery
100 N. Academy Ave
Danville, PA 17822-2130

If you decide to stop participating in the research study, we encourage you to talk to the principal investigator first.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the research study, contact the study doctor Dr. C Liam Dwyer at 570-271-6541 or 570-271-6211 (24-hour hospital switchboard).

For questions about your rights as a research participant, contact the Human Research Protection Program staff of the Geisinger Institutional Review Board (which is a group of people who review the research to protect your rights) at 570-271-8663.

SIGNATURE

I agree to take part in this research study. By signing this consent form, I have not given up any of my legal rights. You will get a signed copy of this form.

_____

Research Participant's Name (Please Print)

_____ _____

Research Participant's Signature Date

I confirm that the research study was thoroughly explained to the subject. I reviewed the consent form with the subject and answered the subject's questions. The subject appeared to have understood the information.

_____ _____

Person Obtaining Consent Signature Date