Treatment of Pediatric Mid-shaft Clavicle Fractures: A Prospective, Observational Study

February 11, 2019

NCT# NCT03402269

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Treatment of Pediatric Midshaft Clavicle Fractures: A Prospective, Observational Study

Study to be Conducted at: *Greenville Health System*
701 Grove Road
Greenville, SC 29605

University Medical Group- Department of Orthopaedic Surgery
Steadman Hawkins Clinic of the Carolinas
105 Doctors Drive
Greenville, SC 29605

Blue Ridge Orthopaedics
309 E. 1st Avenue, Easley, SC 29640

Medical Center Powdersville-Orthopaedics
11402 Anderson Road, Suite C, Greenville, SC 29611

Steadman Hawkins Clinic of the Carolinas
200 Patewood Dr Suite C100
Greenville, SC 29615

Principal Investigator: *Chris Bray, MD (864) 455-7878*

For legal guardians of minors, please note that any words referring to "you" (such as I, me, myself, you, your, yourself) also refer to "your child" throughout this consent form. Permission from you is required for your child to participate in this study.

KEY INFORMATION
You are being asked to participate in a research study. Participation in a research study is voluntary. The information in this consent form is meant to better inform you so you may decide whether or not to participate in this research study. Please ask the study doctor to explain anything you do not understand.

You have broken collarbone (clavicle). If you agree to participate in this study, we will collect information about your clavicle fracture, treatment, and healing process as part of normal care. You will be asked to follow-up with the study doctors at 1 month, 3 months, 6 months, and one year after your treatment. Range of motion, strength and pain will be collected. You will also be asked to fill out questionnaires at each visit regarding your daily activities and your satisfaction with the treatment and how your shoulder and collar bone look. The questionnaires should take about 10 minutes to complete.

All of the medical procedures that you will receive are part of normal care that you would receive even if you did not participate in this study. Participating in this study will not increase your risk of the physical side effects that could occur after your normal treatments.

The purpose of this study is to see how people recover from clavicle injuries.

The Institutional Review Board of the Greenville Health System has reviewed this study for the protection of the rights of human participants in research studies, in accordance with federal and state regulations.

PURPOSE
You are being asked to participate in this study because you have broken your collarbone (clavicle). The purpose of this study is to see how people recover from these injuries.

A total of 30 participants will be enrolled. You will be asked to participate in this study for 1 year.

HOW THE STUDY WORKS
As part of normal treatment, the study doctor will give you instructions on when and how much weight you can put on your collarbone. The doctor will make this decision based on his/her professional opinion.

If you agree to participate in this study, we will collect information about your clavicle fracture, treatment, and healing process as part of normal care. Range of motion will be carefully measured by a goniometer (an instrument to measure range of motion). Your strength will be measured by a dynamometer (a device that measures force) at each visit. You will be asked to rate your pain on a scale of 0 to 10, with 0 being no pain and 10 being the worst pain that you can imagine. As part of the study, you will also be asked to fill out questionnaires at each visit regarding your daily activities and your satisfaction with the treatment and how your shoulder and collar bone look. The questionnaires should take about 10 minutes to complete.

You will be asked to follow-up with your study doctors at 1 month, 3 months, 6 months, and one year after your treatment. This follow-up schedule is what is normal for patients with injuries like yours. All physical examinations and x-rays will be standard of care. You will be asked to complete the study-related questionnaires at the follow-up visits. If you are unable to make it to your study doctor's office for follow-up, study staff may ask you these questions over the phone, email or may mail them to you.

POSSIBLE RISKS
There are no known medical risks related to participation in this study. The greatest risk is the possible release of your personal health information. Your study records are considered confidential, but absolute confidentiality cannot be guaranteed. This study may result in presentations and publications, but steps will be taken to make sure you are not identified by name.

Some of the questions in the questionnaires that you will be asked to complete as part of the study are personal and may be upsetting to some participants. Your doctor and nurse will be available to discuss these questions should you have a concern or problem. You do not have to answer any questions that you do not want to answer.

POSSIBLE BENEFITS
It is not possible to know whether or not you may benefit from participating in this study. The information gained from this study may be useful and may help others.

ALTERNATIVE (OTHER) TREATMENTS
You can still receive evaluation and treatment for your condition if you do not participate in this study. Discuss any alternative treatments with your regular doctor and/or the study doctor before you decide to participate. The decision is entirely up to you. If you decide not to participate in the study, you will not be penalized or lose any benefits and your decision will not affect your relationship with your doctor or hospital.

Please discuss these choices with your doctor.

NEW INFORMATION
Your doctor will tell you about new information that may affect your willingness to participate in this research study. Alternatives, or other choices, concerning your care will be discussed at that time.

There are no plans to share individual research results with you.

COST TO YOU FOR PARTICIPATING IN THIS STUDY
Study funds will pay for the following items/services required by the research:

- *12 month office visit*
- *12 month clavicle x-rays*

Although study funds will pay for the study-related items and services specified above, there may be study-related services not paid for by the sponsor. We will bill you or your health insurer for routine items and services you would have received even if you did not take part in the research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care. You will be responsible for the cost of any care not covered by insurance or study funds.

If you have any questions or are unsure about costs from taking part in the research, please speak with the study doctor or staff.

PAYMENT FOR PARTICIPATION (if applicable)

To You:
You will be paid to participate in this study. You will receive $25 for completing the final study visit at 1 year. This payment is to cover the cost of your time at the final study visit and will be payable upon successful completion of your follow up visit. You will not be reimbursed for the study treatment procedure, if applicable. You will not be reimbursed for expenses of others traveling with you.

To process your study payment, you will be asked to complete a W-9 form with your name, address, date of birth, and Social Security number. If you receive $600 or more for study participation in this research study, or a combination of studies at Greenville Health System in one tax year, Greenville Health System will send you an IRS form 1099 for tax purposes.

You will be paid via ClinCard, a reloadable debit card. The ClinCard program is owned by a company called Greenphire. The study team will give Greenphire your name, address, date of birth and Social Security number as part of the payment system. Greenphire will only use the information to make sure you get paid.

Greenphire will not use your information for any other purposes, and they will not give or sell your information to any other company. The study team will provide you with more information about the ClinCard program following study enrollment.

To Investigators:
The investigators will not be paid above their regular salaries for conducting this study.

To Institution:
The Greenville Health System is not being paid by the sponsor.

COMPENSATION FOR INJURY AS A RESULT OF STUDY PARTICIPATION
Injuries sometimes happen in research even when no one is at fault. The study sponsor, the Greenville Health System, or the investigators as part of this study have no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the 'Contact for Questions' section of this consent.

VOLUNTARY PARTICIPATION
Participation in this study is completely voluntary. You may refuse to participate or withdraw from the study at any time. If you refuse to participate or withdraw from the study, you will not be penalized or lose any benefits. Your decision will not affect your relationship with your doctor or hospital.

However, if you decide to stop study participation, you are encouraged to talk with your doctor regarding safe removal from the study. Further treatment would be discussed.

If your participation in this research study is stopped, your study doctor will discuss any tests or procedures that might be needed for your health and safety, but you may refuse any or all of these tests or procedures. Following this discussion with your study doctor, you still have the right to refuse any or all of these tests or procedures.

AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION
As part of this research study, the study doctor and his/her research team will keep records of your participation in this study. These study records may be kept on a computer and will include all information collected during the research study, and any health information in your medical records that is related to the research study. The study doctor and his/her research team will use and disclose (release) your health information to conduct this study. To evaluate the results of the study and for compliance with federal and state law, your health information may be examined and copied by the Food and Drug Administration (FDA), other governmental regulatory agencies, the Institutional Review Board of the Greenville Health System, the study sponsor and the sponsor's authorized representative(s). This study may result in scientific presentations and publications, but steps will be taken to make sure you are not identified.

Under federal privacy laws, your study records cannot be used or released for research purposes unless you agree. If you sign this consent form, you are agreeing to the use and release of your health information. If you do not agree to this use, you will not be able to participate in this study.

The right to use your health information for research purposes does not expire unless you withdraw your agreement. You have the right to withdraw your agreement at any time. You can do this by giving written notice to your study doctor. If you withdraw your agreement, you will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to review your health information that is created during your participation in this study. After the study is completed, you may request this information.

Once your health information has been released, federal privacy laws may no longer protect it from further release and use.

If you have any questions about the privacy of your health information please ask the study doctor.

CONTACT FOR QUESTIONS

For more information concerning this study and research-related risks or injuries, or to give comments or express concerns or complaints, you may contact the principal investigator, whose information is included below.

You may also contact a representative of the Institutional Review Board of the Greenville Health System for information regarding your rights as a participant involved in a research study or to give comments or express concerns, complaints or offer input. You may obtain the name and number of this person by calling (864) 455-8997.

Principal Investigator Name: Chris Bray, MD

Telephone Number: 864-455-7878

CONSENT TO PARTICIPATE

The study doctor, _____, has explained the nature and purpose of this study to me. I have been given the time and place to read and review this consent form and I choose to participate in this study. I have been given the opportunity to ask questions about this study and my questions have been answered to my satisfaction. I have been given a copy of the study doctor's Notice of Privacy Practices. I agree that my health information may be used and disclosed (released) as described in this consent form. After I sign this consent form, I understand I will receive a copy of it for my own records. I do not give up any of my legal rights by signing this consent form.

_____
Printed Name of Participant

_____ _____ _____
Signature of Participant Date Time

PARENTAL PERMISSION

_____ _____ _____
Signature of Parent/Guardian Date Time

INVESTIGATOR STATEMENT

I have carefully explained to the participant the nature and purpose of the above study. The participant signing this consent form has (1) been given the time and place to read and review this consent form; (2) been given an opportunity to ask questions regarding the nature, risks and benefits of participation in this research study; and (3) appears to understand the nature and purpose of the study and the demands required of participation. The participant has signed this consent form prior to having any study-related procedures performed.

_____ _____ _____
Signature of Investigator Date Time

Principal Investigator	Phone
Chris Bray, MD	864-455-7878

Co-Investigators	
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