Title: Immediate weight bearing as tolerated versus protected weight bearing in supracondylar distal femur fractures; a prospective study

NCT03167099

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Additional Comments:

The protocol number provided at the beginning of the informed consent form (1408401969), which includes full study title, matches protocol number listed on protocol questionnaire. Matching protocol numbers and full study title provide confirmation that the document is relevant to the study in the record.

Only Minimal Risk
Consent Information and HIPAA Form

Principal Investigator	David Hubbard, MD
Department	Orthopaedics
Protocol Number	1408401969
Study Title	Immediate weight bearing as tolerated versus protected weight bearing in supracondylar distal femur fractures; a prospective study
Co-Investigator(s)	Daniel Bravin, MD; Michelle Bramer, MD; John France, MD; Richard Wardell, MD; Lunden Ryan, MD
Study personnel	Sherri Davis, Alexander Conti

Contact Persons

In the event you experience any side effects or injury related to this research, you should contact Dr. David Hubbard at (304) 293-3900. (After hours call 304-598-4000 and ask for the Orthopaedic Resident on call). If you have any questions, concerns, or complaints about this research, you can contact Dr. David Hubbard at (304) 293-3900.
For information regarding your rights as a research subject, to discuss problems, concerns, or suggestions related to the research, to obtain information or offer input about the research, contact the Office of Research Compliance at (304) 293-7073.

Introduction

You, _____, have been asked to participate in this research study, which has been explained to you by _____. This study is being conducted by David Hubbard, MD; Daniel Bravin, MD; Michelle Bramer, MD; John France, MD; Richard Wardell, MD; and Lunden Ryan, MD in the Department of Orthopaedics at West Virginia University.

Purpose(s) of the Study

You are going to have or have had surgery to repair a distal femur fracture. The purpose of this study is to follow patients who have been assigned to either partial weight bearing or full weight bearing after distal femur fracture surgery. Both assignments are standard of care. We want to measure healing rate, pain, flexion, complications (if any), walking status, and other characteristics related to recovery after distal femur fracture surgery.

Description of Procedures

This study involves a group assignment to either partial weight bearing or full weight bearing after surgery to repair a distal femur fracture. It involves all standard of care procedures at all standard of care follow up appointments which include 2 weeks, 6 weeks, 3, 6, and 12 months. It involves answering questions from the patient reported outcome questionnaire, which you will have completed per standard of care at all previous follow up visits via a computer tablet. The phone call will take approximately 15 minutes to answer the questions. You do not have to answer all the questions.

Discomforts

There are no known or expected risks from participating in this study, except for the mild frustration associated with answering the questions.

Alternatives

You do not have to participate in this study.

Benefits

You may not receive any direct benefit from this study. The knowledge gained from this study may eventually benefit others.

Financial Considerations

There is no cost to you for participating in the study. There are no payments to you for participating in the study.

Confidentiality

Any information about you that is obtained as a result of your participation in this research will be kept as confidential as legally possible. Your research records and test results, just like hospital records, may be subpoenaed by court order or may be inspected by the study sponsor or federal regulatory authorities without your additional consent.

HIPAA

We know that information about you and your health is private. We are dedicated to protecting the privacy of that information. Because of this promise, we must get your written authorization (permission) before we may use or disclose your protected health information or share it with others for research purposes.

You can decide to sign or not to sign this authorization section. However, if you choose not to sign this authorization, you will not be able to take part in the research study. Whatever choice you make about this research study will not have an effect on your access to medical care.

Persons/Organizations Providing the Information

Patient/West Virginia University Hospitals

Persons/Organizations Receiving the Information

- The research site(s) carrying out this study. This includes UHA or UHA Affiliated, WVU, WVU Hospitals. It also includes each site's research staff and medical staff
- Health care providers who provide services to you as part of this research study.
- Laboratories and other people and groups that look into your health information as part of this study in agreement with the study protocol.
- The United State Department of Health and Human Services (which includes the National Institutes of Health (NIH), Food and Drug Administration (FDA)) and other groups that have the right to use the information as required by law.
- The members and staff of any Institutional Review Board (IRB) that oversees this research study.
- West Virginia University Office of Research Compliance and Office of Sponsored Programs.

The Following Information Will Be Used

Information from your existing medical records and new information about you that is created or collected during the study such as: history and physicals, clinic visit notes, nursing and staff notes, laboratory results, x-rays, EKG results, demographic data, pulmonary tests, imaging scans and study forms.

The Information is Being Disclosed for the Following Reasons

Publication of study results (without identifying you)

You May Cancel this Authorization at Any Time by Writing to the Principal Investigator

David Hubbard, MD, West Virginia University, Department of Orthopaedics, PO Box 9196, 3400 Health Science South, Morgantown, WV 26506-9196

If you cancel this authorization, any information that was collected already for this study cannot be withdrawn. Once information is disclosed, according to this authorization, the recipient may redisclose it and then the information may no longer be protected by federal regulations.

You have a right to see and make copies of your medical records. You will not be able to see or copy your records related to the study until the sponsor has completed all work related to the study. At that time you may ask to see the study doctor's files related to your participation in the study and have the study doctor correct any information about you that is wrong.

This authorization will expire at the end of the study unless you cancel it before that time.

Voluntary Participation

Participation in this study is voluntary. You are free to withdraw your consent to participate in this study at any time.

Refusal to participate or withdrawal will involve no penalty to you. Refusal to participate or withdrawal will not affect your future care, or your employee status at West Virginia University.

In the event new information becomes available that may affect your willingness to participate in this study, this information will be given to you so that you can make an informed decision about whether or not to continue your participation.

You have been given the opportunity to ask questions about the research, and you have received answers concerning areas you did not understand.

Upon signing this form, you will receive a copy.

I willingly consent to participate in this research.

Signatures

Signature of Subject

_____

Printed Name Date Time

_____

The participant has had the opportunity to have questions addressed. The participant willingly agrees to be in the study.

Signature of Investigator or Co-Investigator

_____

Printed Name Date Time

_____