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

NCT03167099

Document Date: September 11, 2019

Additional Comments:

The date specified in the top left corner of the study protocol is indicative of the date that the document was exported from our IRB software system. It is not reflective of the document date which is 11SEP2019.

Our IRB software system does not provide a full study title on the protocol questionnaire. The protocol number provided at top of protocol questionnaire (1408401969) matches protocol number listed on informed consent form which includes full study title. Matching protocol numbers provide confirmation that the document is relevant to the study in the record.

West Virginia University - Office of Research Integrity and Compliance
Protocol Number: 1408401969
Principal Investigator: David Hubbard

Protocol Questionnaire

Human Subject Research

Does the protocol meet the federal definition of research? For help determining the type of research you are conducting, see the DHHR Human Subject Regulations Decision Charts at http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html.
Yes

Does the research involve living person(s)?
Yes

Will information from individual person(s) be collected as part of this research?
Yes

Funding Source

Is there a secured funding source?
No

Locations of Research

Select the location(s) where the research will be conducted. At least one location must be selected.
Physicians Office Center (POC)

Select the location(s) where the research will be conducted. At least one location must be selected.
WVU Campus

Select the location(s) where the research will be conducted. At least one location must be selected.
Ruby Memorial Hospital or Other WVU Healthcare Site

Will the research take place at an off campus location?
No

Will this study require an Inter-Institutional Authorization Agreement (IAA)?
No

Design

Please provide a lay summary (written at 6th grade level) that includes a statement about the purpose and the general aims of the research.
This study is designed to examine if immediate weight bearing on a distal femur fracture fixed with a primary locking plate, either a distal condylar locking plate or a LISS (less invasive stabilization system), is safe and promotes more rapid fracture healing. Historically and currently patients are kept partial weight bearing after fixation of these fractures for 6-12 weeks until callous formation is observed on radiographs. Our hypothesis is that patients that are allowed to bear weight immediately will heal at least as quickly as those that have their weight bearing status protected with the added benefits from early mobilization. Fracture healing will be monitored closely by follow up appointments and complications will be documented.

Fully describe all procedures to be performed, from start to finish, numbering your procedures 1,2,3 or A, B, C (e.g., 1. Recruiting, 2. Consent, 3. Collecting data, 4. How findings will be shared, etc.).
1.Patients will come to the Emergency Department or the POC after a supracondylar fracture or periprosthetic distal femur fracture. 2. If they fit all the inclusion and none of the exclusion criteria they will be told about the study either before their surgery if they are lucid, not in pain and can understand the study, or after their surgery when they are lucid, not in pain and can understand the study. If they are not lucid, are in pain, or cannot understand the study during this time they will not be offered participation in the study. 3. They will be told about the study with the understanding that assignment to either partial weight bearing or full weight bearing is standard of care and that physical therapy will conduct the therapy based on their group assignment 4. All questions will be answered and the subject will be given the opportunity to consent 5. They will have a metabolic bone work up done if they are 65 years of age or older which is standard of care. 6. Radiographs will be taken at 6 weeks, 3, 6 and 12 months to determine radiographic healing and/or complications with hardware which is standard of care. 7. Two independent surgeons will review radiographs to determine bridging of 3 or 4 cortices 8. We will measure time to ambulation at 2 weeks, 6 weeks and 3 months. Other variables measured include: Age, gender, date of surgery, Surgeon, Rt/Left, plate (LISS or Locking), smoking status, co-morbidities, perambulatory status, PT participation, time to discharge, discharge disposition, return to baseline ambulation, time to union, pain, Knee society score, knee flexion, radiographic evidence of healing, non-union, malunion, infection, DVT, PE, implant failure/reoperation, Vit D level, death. 9. Patients will complete a health progress report at 2 weeks, 3, 6, and 12 months post-surgery which is standard of care.

Please describe the investigational procedures that will be performed throughout the duration of the study.
Reviewing who heals faster with better outcomes based on assignment to full or partial weightbearing, both of which are standard of care, but for the study, the subject is assigned to one or the other.

Please describe the standard of care procedures that will be performed throughout the duration of the study.
Surgery and anything associated with it.

Will you be assigning or randomizing participants to groups or conditions (e.g., control, placebo)?
Yes

Describe the group assignment.
We will be looking at two groups: those with periprosthetic distal femur fracture and those with a distal femur fracture proximal to the native knee. Both will have had their distal femur fracture repaired per standard of care. Patients in both groups will then be randomized into two groups: those allowed to bear weight immediately post operatively and those with protected weight bearing post operatively.

Does the research involve surveys/interviews/questionnaires? If so, attach a copy of the interview/survey questions on the Notes & Attachments page.
No

Describe what is known about this topic and why this study is needed. Please include at least two reference citations to support your rationale.
This study is designed to examine if immediate weight bearing on a distal femur fracture fixed with a primary locking plate, either a distal condylar locking plate or a LISS (less invasive stabilization system), is safe and promotes more rapid fracture healing. Historically and currently patients are kept partial weight bearing after fixation of these fractures for 6-12 weeks until callous formation is observed on radiographs. Our hypothesis is that patients that are allowed to bear weight immediately will heal at least as quickly as those that have their weight bearing status protected with the added benefits from early mobilization. Fracture healing will be monitored closely by follow up appointments and complications will be documented. See Lit Review under Notes and Attachments for Scientific Rationale and references.

What method are you going to use to analyze the data?
Descriptive statistics will be performed on the following variables in both groups: Age, gender, date of surgery, Surgeon, Rt/Left, plate (LISS or Locking), smoking status, co-morbidities, perambulatory status, PT participation, time to discharge, discharge disposition, return to baseline ambulation, time to union, pain, Knee society

score, knee flexion, radiographic evidence of healing, non-union, malunion, infection, DVT, PE, implant failure/reoperation, Vit D level, death.

Expedited Review

Is this study only minimal risk?
Yes

Does the research qualify for Expedited Review Category 1 - clinical studies of FDA-approved drugs or medical devices? (See More Information)
No

Does the research qualify for Expedited Review Category 2 - blood sample collection? (See More Information)
No

Does the research qualify for Expedited Review Category 3 - noninvasive collection of biological specimens? (See More Information)
No

Does the research qualify for Expedited Review Category 4 - noninvasive standard of care procedures? (See More Information)
No

Does the research qualify for Expedited Review Category 5 - evaluation of data (e.g., medical records review)? (See More Information)
Yes

Does the research qualify for Expedited Review Category 6 - voice, video, digital, or image recordings? (See More Information)
No

Does the research qualify for Expedited Review Category 7 - behavior, surveys, interviews, etc.? (See More Information)
No

Briefly describe how the research meets the requirements of the expedited category(ies) selected.
Full or partial weight bearing after a supracondylar distal femur fracture is standard of care. Review of medical records to determine the variables we want to collect; standard of care patient reported outcomes at regular follow up visits.

Does the study involve intervention and/or manipulation of the subjects or the subjects' environment (e.g., educational intervention or training, experimental or quasi-experimental design)?
No

Is the research categorized as interventional medical research?
No

Will subjects intentionally be deceived as to the purpose of the study?
No

HIPAA

Does the research involve protected health information (PHI) or personally identifiable information (PII)?
Yes

Will the HIPAA and consent forms be combined? If not, attach a separate HIPAA Authorization Form to the Notes & Attachments page.
Yes

Are you requesting a HIPAA waiver? If yes, attach a HIPAA Waiver Form on the Notes & Attachments page.
No

Will you be transferring or receiving identifiable data or samples in collaboration with another institution? If yes, attach a signed HIPAA data use/data sharing agreement or Material Transfer Agreement (MTA) or a Biological Material Transfer Agreement to the Notes & Attachments page.
No

Will the research conducted at a covered entity involve only de-identified data? If yes, attach a HIPAA De-Identification Certification Form on the Notes & Attachments page.
No

Will the study involve only non-living individuals? If yes, attach a HIPAA Decedents Form on the Notes & Attachments page.
No

Subjects

Indicate the maximum number of subjects to be enrolled or medical records to be reviewed at all sites by the WVU or VAMC research team.
150

Provide a rationale for choosing your sample size.
75 in each group provides 80% power to detect a difference between the groups.

State the requirement(s) to become a participant in the study (e.g., age range, sex, language spoken, class enrollment/ranking).
All patients aged > 18 yo with a distal supracondylar femur fracture will be included, both male and female; Supracondylar distal femur fractures treated with a locked plate, either a distal condylar locking plate or a LISS (less invasive stabilization system), including peri-prosthetic fractures. CPT code 27511

Explain why selection of participants will be equitable addressing gender, ethnicity, and/or race of subjects.
Patients with an intracondylar split, polytrauma patients with associated trauma that will inhibit their ability to weight bear, metastatic disease, incomplete follow up, those with questionable ability to bear weight (ie advanced dementia), open fractures with bone loss, will not be included. Those who are in pain, not lucid, or unable to understand the study at time of consent will not be included.

In outline format and chronological order, describe what will be done to identify and recruit participants (e.g., A, B, C or 1, 2, 3).
1. Patients will come to the Emergency Department or the POC after a supracondylar fracture or periprosthetic distal femur fracture. 2. If they fit all the inclusion and none of the exclusion criteria they will be told about the study either before their surgery if they are lucid, not in pain and can understand the study, or after their surgery when they are lucid, not in pain and can understand the study. If they are not lucid, are in pain, or cannot understand the study during this time they will not be offered participation in the study.

Will any of the subjects be less than 18 years old?
No

Will your study target populations such as pregnant women, fetuses, neonates, or any groups likely to be vulnerable to coercion or undue influence such as children, prisoners, individuals with impaired decision-making capability or economically or educationally disadvantaged persons?
No

Does this research involve participants who could be coerced or unduly influenced, such as current students/employees of research team members?
No

Does the protocol deal with cancer prevention, treatment, or diagnosis (including surveys)?
No

Has this protocol been reviewed by Clinical Trials Working Group (CTWG)? If yes, please attach the CTWG's correspondence on the Notes & Attachments page.
No

Consent Procedures

Will SIGNED informed consent be obtained from subjects (paper-based and/or electronic)?
Yes

Will the informed consent form be translated into any other language(s)?
No

Is a waiver of informed consent being requested (i.e., there will be no consent process at all)?
No

Is a waiver of the requirement to obtain written documentation of the consent process being requested (if yes, attach the information to be provided to the participants)?
No

Are you requesting an alteration of consent (e.g., short form, braille consent or witnessed verbal consent)?
No

For remote or in-person electronic consent, complete an e-IC worksheet from the OHRP Forms page and attach it to the submission.
If only paper-based in-person consent will be used, describe the consent process. Address the following separately:

1. When will prospective participants be approached for consent?
2. Where will the consent occur?
3. How will the research and the consent materials be explained, and how and when will questions be answered?

. Patients will come to the Emergency Department or the POC after a supracondylar fracture or periprosthetic distal femur fracture. 2. If they fit all the inclusion and none of the exclusion criteria they will be told about the study either before their surgery if they are lucid, not in pain and can understand the study, or after their surgery when they are lucid, not in pain and can understand the study. If they are not lucid, are in pain, or cannot understand the study during this time they will not be offered participation in the study. 3. They will be told about the study with the understanding that assignment to either partial weight bearing or full weight bearing is standard of care and that physical therapy will conduct the therapy based on their group assignment 4. All questions will be answered and the subject will be given the opportunity to consent.

Indicate who will be consenting subjects and describe the process of training all personnel who will be obtaining consent.
Research coordinators may consent subjects. They have been trained and have been conducting the consent process for years.

Potential Benefits

Is there any known benefit to the individual subject as a result of participating in the research? Payments to subjects should not be included in this section, but addressed in the Payments/Reimbursements section.
If our hypothesis is correct, those subjects who do full weight bearing will heal faster and suffer less complications.

Describe the potential benefit(s) to society and/or scientific / medical knowledge of the planned work.
Understanding and sharing information gathered from the research study re: benefit or no benefit to full weight bearing after a supracondylar distal femur fracture.

Confidentiality

At any point during this study, will identifiable data be viewed or recorded?
Yes

Data must be kept for a minimum of three (3) years after study completion. In addition to the required 3 years, how much longer will the data be kept?
no longer than 3 years

Where will data be securely located?
On a coded spreadsheet, on the password protected computer of a research team member in the Dept of Orthopaedics.

How will data be destroyed?
Erasing it from the computer.

Will anyone other than the PI, research team members, or IRB have access to the identifiable data (e.g., sponsor/funding source, other collaborators)?
No

Describe the steps that will be taken to maintain the privacy of subjects (e.g., where interaction takes place) and the confidentiality of data (e.g., master code).
A coded spreadsheet has been developed onto which all the data gathered will be placed. An identifier spreadsheet has been developed and will be kept separate from the coded spreadsheet.

Does this study have a Federal Certificate of Confidentiality? If yes, attach the certificate on the Notes & Attachments page.
No

Financial Considerations

Will the subjects incur any costs to participate in this project (e.g., travel, physician fees, study procedures, study drugs)?
No

Will the subject be paid (money, gift certificates, coupons, etc.) to participate in this research project?
No

Will WVU students receive extra credit for participating in this research project?
No

Advertisements

Will there be advertisements for this study?
No

Sample Collection

Will sample(s) be used?
No

Biological Safety

Does the study involve the handling of any infectious and/or non-infectious agents or recombinant DNA?
No

Data Protection for IRB

Does the project have data protection requirements?
No

Protocol Notes

DATE	AUTHOR	TOPIC	NOTE
09/10/2019 02:45 PM	Sherri Davis	A004	add study personnel Alexander Conti
09/05/2019 03:22 PM	Sherri Davis	response to revisions	retired study personnel have been removed from ICF
08/23/2019 02:09 PM	Sherri Davis	renewal 05	removed a study personnel due to retirement
06/18/2015 04:25 PM	Sheila Rye	amendment	the following changes have been made to Design/Procedures, Consent Procedures, and the Consent form: 1. Patients will come to the Emergency Department or the POC after a supracondylar fracture or periprosthetic distal femur fracture. 2. If they fit all the inclusion and none of the exclusion criteria they will be told about the study either before their surgery if they are lucid, not in pain and can understand the study, or after their surgery when they are lucid, not in pain and can understand the study. If they are not lucid, are in pain, or cannot understand the study during this time they will not be offered participation in the study. 3. They will be told about the study with the understanding that assignment to either partial weight bearing or full weight bearing is standard of care and that physical therapy will conduct the therapy based on their group assignment 4. All questions will be answered and the subject will be given the opportunity to consent 5. They will have a metabolic bone work up done if they are 65 years of age or older which is standard of care. 6. Radiographs will be taken at 6 weeks, 3, 6 and 12 months to determine radiographic healing and/or complications with hardware which is standard of care. 7. Two independent surgeons will review radiographs to determine bridging of 3 or 4 cortices 8. We will measure time to ambulation at 2 weeks, 6 weeks and 3 months. Other variables measured include: Age, gender, date of surgery, Surgeon, Rt/Left, plate (LISS or Locking), smoking status, co-morbidities, perambulatory status, PT participation, time to discharge, discharge disposition, return to baseline ambulation, time to union, pain, Knee society score, knee flexion, radiographic evidence of healing, non-union, malunion, infection, DVT, PE, implant failure/reoperation, Vit D level, death. 9. Patients will complete a health progress report at 2 weeks, 3, 6, and 12 months post-surgery which is standard of care. Consent form: Under Purpose: You will have or have had surgery to repair Under Description of Procedures: removed 'except for the 2 week follow up.