STaR (Surgical Timing and Rehabilitation) Trial for Multiple Ligament Knee Injuries

NCT03543098

April 15, 2025

CONSENT FOR ADULTS TO ACT IN A RESEARCH STUDY

TITLE: The STaR Trial
Surgical Timing and Rehabilitation for Multiple Ligament Knee Injuries:
A Multicenter Integrated Clinical Trial
Surgical & Rehabilitation Trial

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SOURCE OF SUPPORT: Department of Defense

STaR TRIAL

Surgical Timing and Rehabilitation for Multiligament Knee Injuries

KEY INFORMATION FOR THE STaR TRIAL

Randomization of Timing for Surgery and Rehabilitation

Prior to joining our research study, the STaR Trial, we want to share key information about the study with you. We want to summarize five topics for you prior to reviewing the consent form.

1. This is a voluntary research study

   You are being asked to take part in this research study because the injury to your knee involves more than one ligament. Participation in this study is completely voluntary and you do not need to participate in the study. If you choose to participate in the study, a study team member will explain the study to you and will answer any questions you might have. You should take your time to make your decision.

2. Summary of Study Activities

   The purpose of this research is to address two questions regarding a multiple ligament knee injury (MLKI).

   Is it best to have surgery shortly after injury or to delay surgery for MLKI?

   Is it best to begin weight bearing and range of motion shortly after surgery or delay it for a few weeks?

   The study will randomize (i.e. a coin toss) when you have surgery and when you begin rehabilitation (early or delayed surgery and early or delayed rehabilitation). The type of surgery is decided between you and your surgeon. Rehabilitation is tailored to the type of surgery you have.

   We will follow-up with you as you undergo treatment. We would like to meet with you at your regularly scheduled office appointments with your surgeon, review your medical records and ask that you fill out questionnaires electronically for 2 years after your surgery.

   You will fill out some questionnaires and have your knee examined at your normal post-surgery appointments with your surgeon that occur approximately 1 week after surgery and 1, 3, 6 and 9 to 12 months after surgery. These visits occur whether or not you choose to participate in the study.

   You will fill out a full set of questionnaires (about 45 minutes to complete) 6, 12, and 24 months after you are randomized to treatment. These can be done from home on the internet.

You will fill out a short survey online every month beginning 6 months after randomization up to 24 months. This should only take 5 to 10 minutes.

We will request your contact information so that we can contact you for these follow-ups. We will also request demographic information for descriptive purposes.

3. Risks and side effects related to timing of MKLI surgery and rehabilitation

   All subjects in this study will undergo surgery and rehabilitation for a multiple ligament knee injury as part of standard of care.

   The risks associated with having early or delayed surgery and early or delayed rehabilitation are not definitively known. The purpose of this study is to find out the best combination of care. It is believed that the risks of early surgery and delayed rehabilitation may include increased joint stiffness and contracture (shortening or hardening of the muscles). The risks of delayed surgery and early rehabilitation may include increased joint laxity (looseness) and instability of the knee.

   Your surgeon will review the overall risks of surgery during your surgical consultation.

4. Reasonable expected benefits

   You may benefit from being followed more closely for the duration of your recovery. This would allow for more timely progression of the post-operative recovery process as well as more timely identification and treatment of any complications associated with multiple ligament knee injuries. This study has the potential to improve the surgical and rehabilitation care for future patients undergoing treatment of a multiple ligament knee injury and you will be contributing to that.

   Additionally, your home rehabilitation exercises will be provided via a website that demonstrates exercises via video and that can easily be updated by your physical therapist.

5. Alternative procedures or treatment

   If you decide that you are not interested in participating in the study, you can continue with your treatment as decided by you and your surgeon. Your participation in this research study will have no effect on your current or future medical care at this hospital or with an affiliated health care provider.

Why is this research being done?
Combat and sports injuries as well as automobile accidents can result in complex knee injuries involving tears of two or more major ligaments. These are referred to as multiple ligament knee injuries (or knee dislocations). Other structures like nerves, blood vessels, tendons and bones may also be injured at the same time. Due to their severity, knee dislocations are difficult to treat and problems after surgery, such as poor healing, stiffness or looseness of the knee, persistent pain, and early arthritis, can be quite common.

Experts agree that surgery is necessary after a knee dislocation, but they do not agree on when to perform surgery or when rehabilitation after surgery should be started. Early surgery for knee dislocations may result in better outcomes but may also be associated with increased joint stiffness. However, delayed surgery may be associated with the knee being too loose.

The best evidence for when to start rehabilitation is based on treatment of anterior cruciate ligament (ACL) injuries in sports, where early post-op rehabilitation is the standard. However, unlike ACL surgery which typically replaces the ACL with a tendon graft, surgeons frequently sew torn ligaments back together after a knee dislocation. Therefore, rehabilitation typically involves protection of the knee by keeping weight off the leg and not allowing the knee to move for 6 weeks, which may delay return to activity.

This study is being conducted to determine when is the best time to do surgery is and when to start rehabilitation after surgery for the treatment of a multiple ligament knee injury.

Who is being asked to participate in this study?
You are being asked to participate in this study because you are between 16 and 55 years old and have presented to your orthopaedic surgeon with a multiple ligament knee injury involving two or more ligaments that requires surgery. If you participate in this study the timing of your surgery and your post-operative rehabilitation will be randomized. Randomization is a process that assigns you by chance, rather than by choice, to either the early or delayed surgery and early or delayed rehabilitation groups. Randomization is like the flip of a coin and gives you equal possibility of being in either group. We will use a computer program to randomly assign you to one of the groups. If you elect not to be in this research study, your surgery and rehabilitation will continue as scheduled, and you, in consultation with your surgeon, will determine when to perform surgery and when to begin rehabilitation.

If you elect to participate in the study that randomizes both the timing of surgery and timing of rehabilitation you will be randomized to one of four groups:

1) early surgery and early rehabilitation;
2) early surgery and delayed rehabilitation;
3) delayed surgery and early rehabilitation;
4) delayed surgery and delayed rehabilitation.

The early and delayed groups are defined as follows:

- Early surgery will be defined as surgery to treat your knee ligament injury within 6 weeks of the date of injury;

- Delayed surgery will be defined as surgery to treat your knee ligament injury 12-16 weeks after injury;
- If you are assigned to the early rehabilitation group you will be allowed to bear weight on your surgical leg and perform range of motion exercises without restrictions starting after your first post-operative appointment with the surgeon (usually 7 to 10 days after surgery);
- If you are assigned to the delayed rehabilitation group you will wear a brace that is locked to keep you knee straight and you will not be allowed to bear weight on the surgical leg or perform range of motion exercises for the first 4 weeks after surgery. After the fourth week, you will gradually put more weight on your leg and perform motion exercises through the full range of motion.

After four weeks, both the early and delayed rehabilitation groups will follow the same rehabilitation procedures.

What procedures will be performed for research purposes?
The following activities will be performed prior to surgery for your multiple ligament knee injury:

Contact Information
We will ask you for your contact information including your name, date of birth, address, phone number, and email address. This information will be shared with investigators at the University of Pittsburgh, so that they can contact you throughout this research study.
(5 minutes to complete)

Demographic Information
Demographic information that will be recorded include your age, sex, weight, height, body mass index (BMI), education level, sports activity level, work activity, military duty, marital status, and smoking history. This form will be completed at the pre-treatment visit.
(5 minutes to complete)

Activity Level Questionnaires
The following questionnaires will be completed at the pre-treatment and follow-up visits. (10 minutes to complete)

- The Occupational Rating Scale of the Cincinnati Knee Rating System measures work activity by rating the duration or frequency of sitting, standing, walking, squatting, climbing, lifting, and carrying performed while working at a job.
- The Marx Sports Activity Scale consists of four activities (running, cutting, decelerating, and pivoting) rated in terms of how often you perform the activity.

Medical History and Physical Examination

A standard of care medical history and physical examination will be performed for all subjects in this study at the pre-treatment visit. The medical history will include a review of your chief complaint, history of present injury, past medical history, allergies, medications, and social and family history. The physical examination will record your knee range of motion, results of any additional medical testing, and the function of your nerves and arteries. Your knee joint laxity(joint looseness) will be assessed by your doctor. The examination involves moving your lower leg forward, backward and side-to-side to determine stability of your knee joint. The physical examination is done for normal clinical purposes but will be recorded for research purposes.(15 minutes to complete)

Surgical Procedure

All surgeries will be performed according to established standards of care for individuals undergoing multiple ligament reconstructions of the knee. ***The timing of your surgery will be scheduled within the guidelines of the group to which you were assigned.*** The details of your surgery will be recorded for the study, including measurements, findings during the arthroscopic examination, and any surgical treatment that you receive for your knee injury.

Post-Operative Rehabilitation

After surgery, you will be referred to a qualified physical therapist to begin your post-operative rehabilitation (physical therapy). ***You will be randomized to receive early rehabilitation or delayed rehabilitation.*** Your physical therapist, in consultation with your surgeon, will be given a set of instructions that will assist them to plan your rehabilitation program as assigned. The investigators of this study will ask your physical therapist to submit information to the investigators regarding your rehabilitation sessions for this study.

Post-Operative Clinical Visits

As part of your standard treatment, you will see your orthopaedic surgeon in the office several times after your surgery. During those visits, your doctor will ask you about your symptoms and level of pain, the appearance of your surgical incisions, your ability to put weight on your surgical leg and the function of your surgical leg. The doctor will also measure the range of motion of your knee, and ask about additional medical tests or surgery you may have had since your last visit. Your knee joint laxity (joint looseness) may also be assessed by your doctor. The examination involves moving your lower leg forward, backward and side-to-side to determine stability of your knee joint. This information will be collected approximately 1 week, and 1, 3, 6, and 9-12 months after your surgery during your regularly scheduled follow-up visits with your surgeon.

Study Questionnaires

You will be asked to complete several questionnaires using a computer. The questionnaires will take approximately 45 minutes to complete. You will complete the questionnaires when you sign this form, prior to your surgery (if surgery is more than four weeks after you sign this form) and 6, 12, and 24 months after your surgery.

The questionnaires will ask about your knee injury, physical symptoms you may be experiencing, your ability to return to military duty (if applicable), work and/or sports, lifestyle and activity level, job function, function during daily living, knee related quality of life, resilience, re-injury to your knee, activity limitations and participation restrictions that you experience due to your knee, and any apprehension that you may have related to your knee.

You will complete several questionnaires (PROMIS Global 10 and Multiple Ligament Quality of Life Questionnaire) that inquire about behavioral health status. We will review your answers to the questionnaires that pertain to your behavioral health and if needed we will provide feedback to you regarding treatment options. If your answers to these questions raise concerns for your immediate safety, we will assist you in facilitating immediate evaluation at the emergency room or through a crisis center.

Survey of Rehabilitation Activities
At 1, 3, and 6 months after surgery you will be asked to complete a short survey that asks about activities you are performing, how much weight you put on your leg, and how much you have been moving your knee. The link to this questionnaire may be sent by text message or email or may be completed when you see your surgeon.
(10 minutes to complete)

Return to Activity Survey
Starting 6 months after your enrollment in this study and continuing monthly, you will be asked to complete a short series of questions that ask about your ability to return to military duty, work, or sports. The link to this questionnaire may be sent by text message or email. (10 minutes to complete)

Review of Medical Records
We are also requesting your authorization or permission to review your medical records; this authorization is valid for an indefinite period of time. If you participate in this study, we will record past, current and/or future identifiable medical information from your hospital and/or other (e.g., physician office) records. The information that will be recorded will be limited to information concerning the purpose of the treatment you underwent for your multiple ligament knee injury including: your medical care, non-operative treatment, surgical treatment, physical therapy information, any follow-up care related to your knee, and information from radiographs and MRI of your lower extremities. No research-derived information will be placed into your medical record. This identifiable medical record information will be made available to members of the research team for an indefinite period of time.

This information will be collected for all office visits related to your knee injury that you have with your physician and physical therapist.

What are the possible risks, side effects, and discomforts of this research study?
Breach of Confidentiality

Although every reasonable effort has been taken, confidentiality during Internet communication activities cannot be guaranteed and it is possible that research information, and additional information beyond that collected for research purposes, may be captured and used by others not associated with this study.

You will not be identified in any publications or presentation of the research results.

Any paper records generated for this study will be assigned a case number. Information collected in this study will be stored in a locked file cabinet and/or on a password protected electronic database and will be accessible only to the research staff. The list linking the code number with your identity will be stored in a separate secure location.

We will protect the privacy and confidentiality of your records, as described in this document, but cannot guarantee the confidentiality of your research records, including information obtained from your medical records, once your personal information is disclosed to others outside UPMC or the University.

Risks of Early/Late Surgical Procedure and Early/Late Rehabilitation

All subjects in this study will undergo surgical treatment for a multiple ligament knee injury as part of standard of care. Therefore, you will sign a separate consent form for the surgical procedure.

The risks associated with having early/delayed surgery or early/delayed rehabilitation are not definitively known. The purpose of this study is to find out the best combination of care. It is believed that the risks of early surgery and delayed rehabilitation may include increased joint stiffness and contracture (shortening or hardening of the muscles). The risks of delayed surgery and early rehabilitation may include increased joint laxity (looseness) and instability of the knee.

What are the possible benefits from taking part in this study?

Participants in this study may benefit from being followed-up more closely during the conduct of the study. This would allow for more timely progression of the post-operative recovery process as well as more timely identification and treatment of any complications associated with multiple ligament knee injuries. This study has the potential to improve the surgical and rehabilitation care for future patients undergoing treatment of a multiple ligament knee injury.

Additionally, your physical therapist will provide you with a home exercise program from a website called MedBridge.com. This program will include written and video instructions for how your exercises should be performed. It will also include some written information that will help you in your recovery and return to activity. This may be of benefit to you if you can not get to physical therapy consistently or if your insurance coverage runs out.

If I agree to take part in this research study, will I be told of any new risks that may be found during the study?

You will be promptly notified if, during the conduct of this research study, any new information about the treatment for multiple ligament knee injuries is found.

Will my insurance provider or I be charged for the costs of any procedures performed as part of this research study?
Neither you, nor your insurance provider, will be charged for the costs of any of the procedures performed exclusively for the purposes of this research study, for example completion of study-related questionnaires or surveys. You or your insurance company will be billed in the standard manner for routine care; including the surgery, post-operative physical therapy, and follow-up visits with your physician. You will be responsible for costs not covered by your insurance carrier. These costs include any applicable co-payments, coinsurances, and deductibles.

Who will pay if I am injured as a result of taking part in this study?
The investigators and their associates who provide medical services recognize the importance of your voluntary participation in their research studies. These individuals and their staff will make reasonable efforts to minimize, control, and treat any injuries that may arise as a result of this research. If you believe you were injured as a result of the research procedures being performed, please contact immediately the Principal Investigator or one of the co-investigators listed on the first page of this form.

Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you. It is possible that your insurance provider will be billed for the costs of this emergency treatment, but none of these costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care unless otherwise specifically stated below. There is no plan for monetary compensation. You do not, however, waive any legal rights by signing this form.

Will I be paid if I take part in this research study?
You will be paid up to $400 for completing all activities related to the research study. You will be paid by the local research team. The payment schedule will be as follows:

- Informed Consent & Screening -- $50
- Baseline Study Questionnaires -- $55

The payment schedule will be as follows by investigators at the University of Pittsburgh:

- Follow-up study Questionnaires
    - 6-months after randomization -- $35
    - 12-months after randomization -- $35
    - 24-months after randomization -- $35
- Survey of Rehabilitation Activities
    - 1-month after surgery -- $10
    - 3-month after surgery -- $10
    - 6-month after surgery -- $10

- Return to Activity Survey
    - 7-11 months after randomization & 13-23 months after randomization -- $10 each time the survey is completed.

Who will know about my participation in this research study?
Any information about you obtained from this research will be kept as confidential (private) as possible. All records related to your involvement in this research study will be stored in a locked file cabinet and/or in a password protected electronic database that will be only accessible to the investigators and their staff. Your identity on these records will be indicated by a case number rather than by your name, and the information linking these case numbers with your identity will be kept separate from the research. You will not be identified by name in any publication of the research results unless you sign a separate consent form giving your permission (release).

To know the physical therapy treatments that you received,we will need to communicate with your physical therapist. We will discuss that you are participating in this study, and your signature below indicates that you agree to this communication. The information that we exchange with the physical therapist will only be related to treatment of your multiple ligament knee injury.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Will this research study involve the use or disclosure of my identifiable medical information?
This research study will involve the recording of current and/or future identifiable medical information from your hospital and/or other (e.g., physician office) records. The information that will be recorded will be limited to information needed to conduct this research project.

Who will have access to identifiable information related to my participation in this research study?
In addition to the investigators listed on the first page of this authorization (consent) form and their research staff, the following individuals will or may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study:

- Investigators from the University of Pittsburgh may review your identifiable research information (which may include your identifiable medical information) for the purpose conducting and monitoring of this research study.

- Authorized representatives of the sponsor of this research study, US Army Medical Research and Development Command, may review your identifiable research information (which may include your identifiable medical information) for the purpose conducting and monitoring of this research study.

- Authorized representatives of the Research Conduct and Compliance Office may review your identifiable research information (which may include your identifiable medical information) for the purpose of monitoring the appropriate conduct of this research study.

- Information collected from this study may be shared with other investigators interested in knee injuries. The information that will be shared will be de-identified, i.e. coded and the information linking the code with your identity will be stored in a separate secure location.

- Authorized representatives of the UPMC hospitals or other affiliated health care providers may have access to identifiable information (which may include your identifiable medical record information) related to your participation in this research study for the purpose of (a) fulfilling orders, made by investigators, for hospital and health care services (e.g. laboratory tests, diagnostic procedures) associated with research participation; (b) addressing correct payment for tests and procedures ordered by the investigators; and/or (c) for internal hospital operations (i.e. quality assurance).

- In unusual cases, the investigators may be required to release identifiable information (which may include your identifiable medical information) related to your participation in this research study in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by state (or provincial) law, the appropriate agencies.

For how long will the investigators be permitted to use and disclose identifiable information related to my participation in this research study?
The investigators may continue to use and disclose, for the purposes described above, identifiable information (which may include your identifiable medical information) related to your participation in this research study for a minimum of 7 years and for as long (indefinite) as it may take to complete this research study.

Is my participation in this research study voluntary?
Your participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above, is completely voluntary. (Note, however, that if you do not provide your consent for the use and disclosure of your identifiable information for the purposes described above, you will not be allowed, in general, to participate in the research study.)

Whether or not you provide your consent for participation in this research study will have no effect on your current or future medical care at this hospital or with an affiliated health care provider.

Your doctor is involved as an investigator in this research study. As both your doctor and a research investigator, s/he is interested both in your medical care and the conduct of this research

study. Before agreeing to participate in this research study, or at any time during your study participation, you may discuss your care with another doctor who is not associated with this research study. You are not under any obligation to participate in any research study offered by your doctor.

May I withdraw, at a future date, my consent for participation in this research study?
You may withdraw, at any time, your consent for participation in this research study (However, if you withdraw your consent for the use and disclosure of your identifiable medical record information for the purposes described above, you will also be withdrawn, in general, from further participation in this research study.)

Any identifiable research or medical information recorded for, or resulting from, your participation in this research study prior to the date that you formally withdrew your consent may continue to be used and disclosed by the investigators for the purposes described above.

To formally withdraw your consent for participation in this research study you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form.

Your decision to withdraw your consent for participation in this research study will have no effect on your current or future relationship with this institution. Your decision to withdraw your consent for participation in this research study will have no effect on your current or future medical care at this institution or with affiliated health care provider.

If I agree to take part in this research study, can I be removed from the study without my consent?
It is possible that you may be removed from the research study by the researchers. You may be removed from the study, for example, if you do not meet all the eligibility criteria prior to randomization or you become non-compliant with the follow-up activities.

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VOLUNTARY CONSENT

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any aspect of this research study during the course of this study, and that such future questions, concerns or complaints will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator.

Any questions I have about my rights as a research participant or the research use of my medical information will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668).

By signing this form, I consent to participate in this research study and provide my authorization to share my medical records with the research team. A copy of this consent form will be given to me.

_____

Participant's Name

_____ _____

Participant's Signature Date

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions, concerns or complaints as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____ _____

Printed Name of Person Obtaining Consent Role in Research Study

_____ _____

Signature of Person Obtaining Consent Date

University of Pittsburgh Medical Center
Department of Orthopaedic Surgery

CONSENT FOR ADULTS TO ACT IN A RESEARCH STUDY

TITLE: The STaR Trial
Surgical Timing and Rehabilitation for Multiple Ligament Knee Injuries:
A Multicenter Integrated Clinical Trial
Rehabilitation Trial

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SOURCE OF SUPPORT: Department of Defense

STaR TRIAL

Surgical Timing and Rehabilitation for Multiligament Knee Injuries

KEY INFORMATION FOR THE STaR TRIAL

Randomization of Timing of Adult Rehabilitation

Prior to joining our research study, STaR Trial, we want to share this key information about the study with you. We want to summarize five topics for you prior to reviewing the consent form.

1. This is a voluntary research study

   You are being asked to take part in this research study because the injury to your knee involves more than one ligament. Participation in this study is completely voluntary and you do not need to participate in the study. If you choose to participate in the study, a study team member will explain the study to you and will answer any questions you might have. You should take your time to make your decision.

2. Summary of Study Activities

   The purpose of this research is to answer a question about rehabilitation after surgery for a multiple ligament knee injury (MLKI).

   Is it best to begin weight bearing and range of motion shortly after surgery or delay it for a few weeks?

   The study will randomize (i.e. a coin toss) when you begin rehabilitation after surgery (early or delayed rehabilitation). Other than timing to begin rehabilitation, the two groups receive the same treatment

   We will follow-up with you as you undergo treatment. We would like to meet with you at your regularly scheduled office appointments with your surgeon, review your medical records and ask that you fill out questionnaires electronically for 2 years after your surgery.

   You will fill out some questionnaires and have your knee examined at your normal post-surgery appointments with your surgeon that occur approximately 1 week after surgery, 1 month, 3 months, 6 months, and 9 to 12 months after surgery. These visits occur whether or not you choose to participate in the study.

   You will fill out a full set of questionnaires (about 45 minutes to complete) at 6, 12, and 24 months after you are randomized to treatment. These can be done from home on the internet.

You will fill out a short survey online every month beginning 6 months after randomization up to 24 months. This should only take 5 to 10 minutes.

We will request your contact information so that we can contact you for these follow-ups. We will request demographic information for descriptive purposes.

3. Risks and side effects related to timing of rehabilitation after surgery for MKLI

   All subjects in this study will undergo surgery and rehabilitation for a multiple ligament knee injury as part of standard of care.

   The risks associated with having early or delayed rehabilitation are not definitively known. The purpose of this study is to find out the best combination of care. It is believed that the risks of delayed rehabilitation may include increased joint stiffness and contracture (shortening or hardening of the muscles). The risks of early rehabilitation may include increased joint laxity (looseness) and instability of the knee.

4. Reasonable expected benefits

   You may benefit from being followed-up more closely for the duration of your recovery. This would allow for more timely progression of the post-operative recovery process as well as more timely identification and treatment of any complications associated with multiple ligament knee injuries. This study has the potential to improve rehabilitation care for future patients undergoing treatment of a multiple ligament knee injury and you will be contributing to that.

   Additionally, your home rehabilitation exercises will be provided via a website that demonstrates exercises via video and that can easily be updated by your physical therapist.

5. Alternative procedures or treatment

   If you decide that you are not interested in participating in the study, you can continue with your treatment as decided by you and your surgeon. Your participation in this research study will have no effect on your current or future medical care at this hospital or with an affiliated health care provider.

Why is this research being done?
Combat and sports injuries as well as automobile accidents can result in complex knee injuries involving tears of two or more major ligaments. These are referred to as multiple ligament knee injuries (or knee dislocations). Other structures like nerves, blood vessels, tendons and bones may also be injured at the same time. Due to their severity, knee dislocations are difficult to treat and problems after surgery, such as poor healing, stiffness or looseness of the knee, persistent pain, and early arthritis, can be quite common. Experts agree that surgery is necessary after a knee dislocation, but they do not agree on when to perform surgery or when rehabilitation after surgery should be started. Early surgery for knee dislocations may result in better outcomes but may also be associated with increased joint stiffness. However, delayed surgery may be associated with the knee being too loose.

The best evidence for when to start rehabilitation is based on treatment of anterior cruciate ligament (ACL) injuries in sports, where early post-op rehabilitation is the standard. However, unlike ACL surgery which typically replaces the ACL with a tendon graft, surgeons frequently sew torn ligaments back together after a knee dislocation. Therefore, rehabilitation typically involves protection of the knee by keeping weight off the leg and not allowing the knee to move for 6 weeks, which may delay return to activity. This study is being conducted to determine when is the best time after surgery to start rehabilitation for the treatment of a multiple ligament knee injury.

Who is being asked to participate in this study?
You are being asked to participate in this study because you are between 16 and 55 years old and have presented to your orthopaedic surgeon with a multiple ligament knee injury involving two or more ligaments that requires surgery. When to perform surgery has already been determined based on the nature of your injury and/or when you first saw the orthopaedic surgeon. If you participate in this study, the timing of your post-operative rehabilitation will be randomized.

Randomization is a process that assigns you by chance, rather than by choice, to either the early or delayed rehabilitation group. Randomization is like the flip of a coin and gives you equal possibility of being in either group. We will use a computer program to randomly assign you to one of the groups. If you elect not to be in this research study, your treatment for your injury will continue as scheduled, and you, in consultation with your surgeon, will determine when to begin rehabilitation.

The timing of post-operative rehabilitation will be randomized to one of two groups:
1) early rehabilitation;
2) delayed rehabilitation.

The early and delayed groups are defined as follows:
- If you are assigned to the early rehabilitation group, you will be allowed to bear weight on your surgical leg and perform motion exercises without restrictions starting after your first post-operative appointment with the surgeon (usually 7 to 10 days after surgery);

- If you are assigned to the delayed rehabilitation group, you will wear a brace that is locked to keep your knee straight and you will not be allowed to bear weight on the surgical leg and or perform range of motion exercises for the first 4 weeks after surgery. After the fourth week, you will gradually put more weight on your leg and perform motion exercises perform motion exercises through the full range of motion.

After four weeks, both the early and delayed rehabilitation groups will follow the same rehabilitation procedures.

What procedures will be performed for research purposes?
The following activities will be performed prior to surgery for your multiple ligament knee injury:

Contact Information
We will ask you for your contact information including your name, date of birth, address, phone number, and email address. This information will be shared with investigators at the University of Pittsburgh, so that they can contact you throughout this research study.
(5 minutes to complete)

Demographic Information
Demographic information that will be recorded includes your age, sex, weight, height, body mass index (BMI), education level, sports activity level, work activity, military duty, marital status, and smoking history. This form will be completed at the pre-treatment visit.
(5 minutes to complete)

Activity Level Questionnaires
The following questionnaires will be completed at the pre-treatment and follow-up visits. (10 minutes to complete)

- The Occupational Rating Scale of the Cincinnati Knee Rating System measures work activity by rating the duration or frequency of sitting, standing, walking, squatting, climbing, lifting, and carrying performed while working at a job.
- The Marx Sports Activity Scale consists of four activities (running, cutting, decelerating, and pivoting) rated in terms of how often you perform the activity.

Medical History and Physical Examination
A standard of care medical history and physical examination will be performed for all subjects in this study at the pre-treatment visit. The medical history will include a review of your chief complaint, history of present injury, past medical history, allergies, medications, and social and family history. The physical examination will record your knee range of motion, results of any additional medical testing, and the function of your nerves and arteries. Your knee joint laxity (joint looseness) will be assessed by your doctor. The examination involves moving your lower leg forward, backward and side-to-side to determine stability of your knee joint. The physical examination is done for normal clinical purposes but will be recorded for research purposes. (15 minutes to complete)

Surgical Procedure
All surgeries will be performed according to established standards of care for individuals undergoing multiple ligament reconstructions of the knee. The details of your surgery will be recorded for the study, including measurements, findings during the arthroscopic examination, and any surgical treatment that you receive for your knee injury.

Post-Operative Rehabilitation
After surgery, you will be referred to a qualified physical therapist to begin your post-operative rehabilitation (physical therapy). ***You will be randomized to receive early rehabilitation or delayed rehabilitation.*** Your physical therapist, in consultation with your surgeon, will be given a set of instructions that will assist them to plan your rehabilitation program as assigned. The investigators of this study will ask your physical therapist to submit information to the investigators regarding your rehabilitation sessions for this study.

Post-Operative Clinical Visits
As part of your standard treatment, you will see your orthopaedic surgeon in the office several times after your surgery. During those visits, your doctor will ask you about your symptoms and level of pain, the appearance of your surgical incisions, your ability to put weight on your surgical leg and the function of your surgical leg. The doctor will measure the range of motion of your knee, and ask about additional medical tests or surgery you may have had since your last visit. Your knee joint laxity (joint looseness) may also be assessed by your doctor. The exam involves moving your lower leg forward, backward and side-to-side to determine stability of your knee joint. This information will be collected approximately 1 week, and 1, 3, 6, and 9-12 months after your surgery during your regularly scheduled follow-up visits with your surgeon.

Study Questionnaires
You will be asked to complete several questionnaires using a computer. The questionnaires will take approximately 45 minutes to complete. You will complete the questionnaires when your sign this form, prior to your surgery (if surgery is more than four weeks after your sign this form) and 6, 12, and 24 months after your surgery.

The questionnaires will ask about your knee injury, physical symptoms you may be experiencing, your ability to return to military duty (if applicable), work and/or sports, lifestyle and activity level, job function, function during daily living, knee related quality of life, resilience, re-injury to your knee, activity limitations and participation restrictions that you experience due to your knee, and any apprehension that you may have related to your knee.

You will complete several questionnaires (PROMIS Global 10 and Multiple Ligament Quality of Life Questionnaire) that inquire about behavioral health status. We will review your answers to the questionnaires that pertain to your behavioral health and if needed we will provide feedback to you regarding treatment options. If your answers to these questions raise concerns for your immediate safety, we will assist you in facilitating immediate evaluation at the emergency room or through a crisis center.

Survey of Rehabilitation Activities
At 1, 3, and 6 months after surgery you will be asked to complete a short survey that asks about activities you are performing, how much weight you put on your leg, and how much you have been moving your knee. The link to this questionnaire may be sent by text message or email or may be completed when you see your surgeon. (10 minutes to complete)

Return to Activity Survey
Starting 6 months after your surgery and continuing monthly until 24 months, you will be asked monthly to complete a short series of questions that ask about your ability to return to military duty, work, or sports. The link to this questionnaire may be sent by text message or email. (10 minutes to complete)

Review of Medical Records
We are also requesting your authorization or permission to review your medical records; this authorization is valid for an indefinite period of time. If you participate in this study, we will record past, current and/or future identifiable medical information from your hospital and/or other (e.g., physician office) records. The information that will be recorded will be limited to information concerning the purpose of the treatment you underwent for your multiple ligament knee injury including: your medical care, non-operative treatment, surgical treatment, physical therapy information, any follow-up care related to your knee, and information from radiographs and MRI of your lower extremities. No research-derived information will be placed into your medical record. This identifiable medical record information will be made available to members of the research team for an indefinite period of time.

This information will be collected for all office visits you had with your physician and physical therapist related to your knee injury.

What are the possible risks, side effects, and discomforts of this research study?
Breach of Confidentiality
Although every reasonable effort has been taken, confidentiality during Internet communication activities cannot be guaranteed and it is possible that research information, and additional information beyond that collected for research purposes, may be captured and used by others not associated with this study.

You will not be identified in any publications or presentation of the research results.

Any paper records generated for this study will be assigned a case number. Information collected in this study will be stored in a locked file cabinet and/or on a password protected electronic database and will be accessible only to the research staff. The list linking the code number with your identity will be stored in a separate secure location.

We will protect the privacy and confidentiality of your records, as described in this document, but cannot guarantee the confidentiality of your research records, including information obtained

from your medical records, once your personal information is disclosed to others outside UPMC or the University.

Risks of Early/Late Rehabilitation

All subjects in this study will undergo surgical treatment for a multiple ligament knee injury as part of standard of care. Therefore, you will sign a separate consent form for the surgical procedure. The risks associated with having early/delayed rehabilitation are not definitively known. The purpose of this study is to find out the best combination of care. It is believed that the risks of delayed rehabilitation may include increased joint stiffness and contracture (shortening or hardening of the muscles). The risks of early rehabilitation may include increased joint laxity (looseness) and instability of the knee.

What are the possible benefits from taking part in this study?

Participants in this study may benefit from being followed-up more closely during the conduct of the study. This would allow for more timely progression of the post-operative recovery process as well as more timely identification and treatment of any complications associated with multiple ligament knee injuries. This study has the potential to improve the surgical and rehabilitation care for future patients undergoing treatment of a multiple ligament knee injury

Additionally, your physical therapist will provide you with a home exercise program from a website called MedBridge.com. This program will include written and video instructions for how exercises should be performed. It will also include some written information that will help you in your recovery and return to activity. This may be a benefit to you if you can not get to physical therapy consistently or if your insurance coverage runs out.

If I agree to take part in this research study, will I be told of any new risks that may be found during the study?

You will be promptly notified if, during the conduct of this research study, any new information about the treatment for multiple ligament knee injuries is found.

Will my insurance provider or I be charged for the costs of any procedures performed as part of this research study?

Neither you, nor your insurance provider, will be charged for the costs of any of the procedures performed exclusively for the purposes of this research study for example completion of study-related questionnaires or surveys. You or your insurance company will be billed in the standard manner for routine care, including surgery, post-operative physical therapy, and follow-up visits with your physician. You will be responsible for costs not covered by your insurance carrier. These costs include any applicable co-payments, coinsurances, and deductibles.

Who will pay if I am injured as a result of taking part in this study?

The investigators and their associates who provide medical services recognize the importance of your voluntary participation in their research studies. These individuals and their staff will make reasonable efforts to minimize, control, and treat any injuries that may arise as a result of this research. If you believe you were injured as a result of the research procedures being performed,

please contact immediately the Principal Investigator or one of the co-investigators listed on the first page of this form.

Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you. It is possible that your insurance provider will be billed for the costs of this emergency treatment, but none of these costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care unless otherwise specifically stated below. There is no plan for monetary compensation. You do not, however, waive any legal rights by signing this form.

Will this research study involve the use or disclosure of my identifiable medical information?
This research study will involve the recording of current and/or future identifiable medical information from your hospital and/or other (e.g., physician office) records. The information that will be recorded will be limited to information concerning the research project.

Will I be paid if I take part in this research study?
You will be paid up to $400 for completing all activities related to the research study. You will be paid by the local research team. The payment schedule will be as follows:

- Informed Consent & Screening -- $50
- Baseline Study Questionnaires -- $55

The payment schedule will be as follows by investigators at the University of Pittsburgh:

- Follow-up study Questionnaires
    - 6-months after surgery -- $35
    - 12-months after surgery-- $35
    - 24-months after surgery -- $35
- Survey of Rehabilitation Activities
    - 1-month after surgery -- $10
    - 3-months after surgery -- $10
    - 6-months after surgery -- $10
- Return to Activity Survey
    - 7-11 months after surgery & 13-23 months after surgery -- $10 each time the survey is completed.

Who will know about my participation in this research study?
Any information about you obtained from this research will be kept as confidential (private) as possible. All records related to your involvement in this research study will be stored in a locked file cabinet and/or in a password protected electronic database that will only be accessible to the investigators and their staff. Your identity on these records will be indicated by a case number rather than by your name, and the information linking these case numbers with your identity will be kept separate from the research data. You will not be identified by name in any publication of the research results unless you sign a separate consent form giving your permission (release).

To know the physical therapy treatments that you received, we will need to communicate with your physical therapist. We will discuss that you are participating in this study, and your signature below indicates that you agree to this communication. The information that we exchange with the physical therapist will only be related to treatment of your multiple ligament knee injury.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Will this research study involve the use or disclosure of my identifiable medical information?
This research study will involve the recording of current and/or future identifiable medical information from your hospital and/or other (e.g., physician office) records. The information that will be recorded will be limited to information needed to conduct this research project.

Who will have access to identifiable information related to my participation in this research study?
In addition to the investigators listed on the first page of this authorization (consent) form and their research staff, the following individuals will or may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study:

- Investigators from the University of Pittsburgh may review your identifiable research information (which may include your identifiable medical information) for the purpose conducting and monitoring of this research study.

- Authorized representatives of the sponsor of this research study, US Army Medical Research and Development Command, may review your identifiable research information (which may include your identifiable medical information) for the purpose conducting and monitoring of this research study.

- Authorized representatives of the Research Conduct and Compliance Office may review your identifiable research information (which may include your identifiable medical information) for the purpose of monitoring the appropriate conduct of this research study.

- Information collected from this study may be shared with other investigators interest in knee injuries. The information that will be shared will be de-identified, i.e. coded and the information linking the code with identity will be stored in a separate secure location.

- Authorized representatives of the UPMC hospitals or other affiliated health care providers may have access to identifiable information (which may include your teenager's identifiable medical record information) related to your participation in this research study for the purpose of (a) fulfilling orders, made by investigators, for hospital and

health care services (e.g. laboratory tests, diagnostic procedures) associated with research participation; (b) addressing correct payment for tests and procedures ordered by the investigators; and/or (c) for internal hospital operations (i.e. quality assurance).

- In unusual cases, the investigators may be required to release identifiable information (which may include your identifiable medical information) related to your participation in this research study in response to an order from a court of law. If the investigators learn that you or someone with whom your teenager is involved is in serious danger or potential harm, they will need to inform, as required by state (or provincial) law, the appropriate agencies.

For how long will the investigators be permitted to use and disclose identifiable information related to my participation in this research study?
The investigators may continue to use and disclose, for the purposes described above, identifiable information (which may include your identifiable medical information) related to your participation in this research study for a minimum of 7 years and for as long (indefinite) as it may take to complete this research study.

Is my participation in this research study voluntary?
Your participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above, is completely voluntary. (Note, however, that if you do not provide your consent for the use and disclosure of your identifiable information for the purposes described above, you will not be allowed, in general, to participate in the research study.)

Whether or not you provide your consent for participation in this research study will have no effect on your current or future medical care at this hospital or with an affiliated health care provider.

Your doctor is involved as an investigator in this research study. As both your doctor and a research investigator, s/he is interested both in your medical care and the conduct of this research study. Before agreeing to participate in this research study, or at any time during your study participation, you may discuss your care with another doctor who is not associated with this research study. You are not under any obligation to participate in any research study offered by your doctor.

May I withdraw, at a future date, my consent for participation in this research study?
You may withdraw, at any time, your consent for participation in this research study (However, if you withdraw your consent for the use and disclosure of your identifiable medical record information for the purposes described above, you will also be withdrawn, in general, from further participation in this research study.)

Any identifiable research or medical information recorded for, or resulting from, your participation in this research study prior to the date that you formally withdrew your consent may continue to be used and disclosed by the investigators for the purposes described above.

To formally withdraw your consent for participation in this research study you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form.

Your decision to withdraw your consent for participation in this research study will have no effect on your current or future relationship with this institution. Your decision to withdraw your consent for participation in this research study will have no effect on your current or future medical care at this institution or with affiliated health care provider.

If I agree to take part in this research study, can I be removed from the study without my consent?

It is possible that you may be removed from the research study by the researchers. You may be removed from the study, for example, if you do not meet all the eligibility criteria prior to randomization or you become non-compliant with the follow-up activities.

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VOLUNTARY CONSENT

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any aspect of this research study during the course of this study, and that such future questions, concerns or complaints will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator.

Any questions I have about my rights as a research participant or the research use of my medical information will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668).

By signing this form, I consent to participate in this research study and provide my authorization to share my medical records with the research team. A copy of this consent form will be given to me.

_____

Participant's Name

_____ _____

Participant's Signature Date

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions, concerns or complaints as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____ _____

Printed Name of Person Obtaining Consent Role in Research Study

_____ _____

Signature of Person Obtaining Consent Date