Protocol Details

Basic Info

Confirmation Number:	**chhbdbbd**
Protocol Number:	**831759**
Created By:	**KEATING, JANE J**
Principal Investigator:	**SEAMON, MARK J**
Protocol Title:	**Clinical Outcomes of Immediate vs. Delayed Fasciotomy in Extremity Trauma**
Short Title:	**Immediate vs. Delayed Fasciotomy in Trauma**
Protocol Description:	**This is a multi-center prospective observational study to determine the effect of fasciotomy timing of fasciotomy related outcomes after extremity injury from trauma. Patients with extremity injury requiring revascularization following penetrating or blunt trauma will be enrolled.**
Submission Type:	**Biomedical Research**
Application Type:	**EXPEDITED Category 4**

Resubmission*
Yes

Study Personnel

Principal Investigator

Name:	**SEAMON, MARK J**
Dept / School / Div:	**4502 - SU-Surgery Administration**
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Phone:	**215-662-7323**
Fax:	**215-243-4679**
Pager:	
Email:	**mark.seamon@uphs.upenn.edu**
HS Training Completed:	**Yes**
Training Expiration Date:	**11/06/2020**
Name of course completed :	**CITI Protection of Human Subjects Research Training - ORA**

Study Contacts

Name:	**SHIROFF, ADAM M**
Dept / School / Div:	**4507 - SU-Trauma**
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Pager:	
Email:	**adam.shiroff@uphs.upenn.edu**
HS Training Completed:	**Yes**
Training Expiration Date:	**04/06/2019**
Name of course completed :	**CITI Protection of Human Subjects Research Training - ORA**

Other Investigator

Name:	**KEATING, JANE J**
Dept / School / Div:	**2100 - Health System**
Campus Address Mail Code	**6070**
Address:	**HARRISON - 313 STMLR** **3450 HAMILTON WK**
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Pager:	
Email:	**Jane.Keating@uphs.upenn.edu**
HS Training Completed:	**Yes**
Training Expiration Date:	**03/13/2021**
Name of course completed :	**CITI Protection of Human Subjects Research Training - ORA**

Responsible Org (Department/School/Division):

4507 - SU-Trauma

Key Study Personnel

None

Disclosure of Significant Financial Interests*
Does any person who is responsible for the design, conduct, or reporting of this research protocol have a **FINANCIAL INTEREST**?
No

Penn Intellectual Property*
To the best of the Principal Investigator's knowledge, does this protocol involve the testing, development or evaluation of a drug, device, product, or other type of intellectual property (IP) that is owned by or assigned to the University of Pennsylvania?
No

Certification
I have reviewed the *Financial Disclosure and Presumptively Prohibited Conflicts for Faculty Participating in Clinical Trials* and the *Financial Disclosure Policy for Research and Sponsored Projects* with all persons who are responsible for the design, conduct, or reporting of this research; and all required Disclosures have been attached to this application.
Yes

Biomedical Research

Clinical Trial*
Is this a clinical trial?
No

Investigator Initiated Trial*
Is this an investigator initiated trial?
No

Drugs or Devices*
Does this research study involve Drugs or Devices?
No

IND Exemption

For studies that fall under an IND exemption, please provide the number below

For studies including IND or IDE's, please provide the number(s) below

IDE Review*
NOTE: For research involving investigational devices, you are required to review the guidance on Managing Research Device Inventory. Consult the Penn Manual for Clinical Research: https://www.med.upenn.edu/pennmanual/secure/investigational-product-management-at-sites-not-using-investigational-drug-services-(ids).html Please check the box Yes if you have reviewed the guidance.
Yes

Research Device Management*
Please indicate how research device(s) will be managed.
Not Applicable (no investigational devices)

Drug, Herbal Product or Other Chemical Element Management *
Please indicate how drugs, herbal products or other chemical entities will be managed.
Not Applicable (no drugs, herbal products or other chemical entities)

Radiation Exposure*
Are research subjects receiving any radiation exposure (e.g. X-rays, CT, Fluoroscopy, DEXA, pQCT, FDG, Tc-99m, etc.) that they would not receive if they were not enrolled in this protocol?
No

Gene Transfer*
Does this research involve gene transfer (including all vectors) to human subjects?
No

Human Source Material*
Does this research include collection or use of human source material (i.e., human blood, blood products, tissues or body fluids)?
No

CACTIS and CT Studies*
Does the research involve Center for Advanced Computed Tomography Imaging Services (CACTIS) and CT studies that research subjects would not receive if they were not part of this protocol?
No

CAMRIS and MRI Studies*
Does the research involve Center for Advanced Magnetic Resonance Imaging and Spectroscopy (CAMRIS) and MRI studies that research subjects would not receive if they were not part of this protocol?
No

Investigational Agent or Device within the Operating Room*
Does the research project involve the use of an investigational agent or device within the Operating Room?
No

Cancer Related research not being conducted by an NCI cooperative group*
Does this protocol involve cancer-related studies in any of the following categories?
No

Processing of Materials*
Will the research involve processing (such as over encapsulating, or compounding)?
No

In-House Manufacturing of Materials*
Will the research involve processing (such as over encapsulating, or compounding)?
No

Medical Information Disclosure*
Does the research proposal involve the use and disclosure of research subject's medical information for research purposes?
No

If the answer is YES, indicate which items is is provided with this submission:

CTRC Resources*
Does the research involve CTRC resources?
No

Pathology and Laboratory Medicine Resources*
Will samples be collected by hospital phlebotomy and/or processed or analyzed by any of the clinical laboratories of the University of Pennsylvania Health System?
No

Research Involves Apheresis, Cell Collection, and/or Blood Product Collection*
Does this research involve collection of blood products in the Penn Donor Center and/or the use of apheresis for treatment or collection of cells or other blood components?
No

Research involving blood transfusion or drug infusions*
Will your research involve blood transfusion or infusion of study drug in 3 Ravdin Apheresis Unit for research purposes?
No

Trial in Radiation Oncology
Is this research a prospective trial being done in Radiation Oncology, and if so, has this protocol been approved by the Radiation Oncology Protocol committee?
N/A

Study in Radiation Oncology
Is this research a retrospective study being done in Radiation Oncology, and if so, has this project been

reviewed by the Radiation Oncology Clinical Research Group?
N/A

Use of UPHS services*
Does your study require the use of University of Pennsylvania Health System (UPHS) services, tests or procedures*, whether considered routine care or strictly for research purposes?
No

Primary Focus*
Research on human data sets (e.g. medical records, clinical registries, existing research data sets, medical administrative data, etc.)

Protocol Interventions

	Sociobehavioral (i.e. cognitive or behavioral therapy)
	Drug
	Device - therapeutic
	Device - diagnostic (assessing a device for sensitivity or specificity in disease diagnosis)
	Surgical
	Diagnostic test/procedure (research-related diagnostic test or procedure)
	Obtaining human tissue for basic research or biospecimen bank
	Survey instrument
x	**None of the above**

The following documents are currently attached to this item:

There are no documents attached for this item.

Sponsors

Business Administrator

none

Department budget code

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Funding Sponsors

Funding sponsors billing address
If you have selected a commercial or industry sponsor, please provide the appropriate address and contact information for the Sponsor for the purposes of billing for IRB review fees (initial review, continuing review and convened modification fees apply here). If the Sponsor is not industry/ commercial, this information is not necessary to provide with your application.

Funding sponsors gift
Is this research being funded by a philanthropic gift?

Regulatory Sponsor

IND Sponsor

none

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Industry Sponsor

None

Project Funding*
Is this project funded by or associated with a grant or contract?
No

Sponsor Funding
Is this study funded by an industry sponsor?

Status of contract

The following documents are currently attached to this item:

There are no documents attached for this item.

Multi-Site Research

Other Sites

No other sites

Management of Information for Multi-Center Research
Data will be collected via REDchart at each institution for each subject enrolled. Unanticipated problems will likely be infrequent given the observational nature of the study, however these will be reported to the Lead Investigator as they arise. Three months into the enrollment of patients, interim results will be evaluated at each institution for brief review.

The following documents are currently attached to this item:

Site Information (redcapsurveylink.docx)

Protocol

Abstract
The optimal timing of fasciotomy following extremity revascularization is unknown. The purpose of this study is to determine the effect of fasciotomy time on fasciotomy related outcomes after extremity injury from trauma. This is a multi-center observational study in which we will enroll patients aged 15 years and older at several level one trauma centers with traumatic extremity injury requiring revascularization. We will then compare clinical outcomes in order to study the optimal timing of fasciotomy following injury.

Objectives

Overall objectives
To determine the effect of fasciotomy time on fasciotoy related outcomes after extremity injury from trauma.

Primary outcome variable(s)
Compare patents who underwent early fasciotomy and those who underwent late fasciotomy differences of complications associated with fasciotomy including compartment syndrome, tissue ischemia, infection, amputation, deep venous thrombosis, pulmonary embolism, ventilator days, intensive care unit length of stay, and hospital length of stay.

Secondary outcome variable(s)
To determine the impact that clinical variables have on fasciotomy-related outcomes.

Background
Extremity fasciotomy is the surgical treatment of acute compartment syndrome and involves the surgical decompression of compartments. Acute compartment syndrome often occurs following both penetrating and blunt trauma. In the case of acute compartment syndrome, fasciotomy is necessary when increased pressure within a compartment reduces the circulation to tissues within that space. The most common sites of compartment syndrome and subsequent fasciotomy are the leg and the forearm following injury to the tibial diaphysis or distal radius. Many injury patterns are associated with the need for fasciotomy, including thermal burns, circumferential constrictive bandages, penetrating trauma, and patients with vascular injuries. Additionally, patients on blood thinning medications or those with underlying bleeding diathesis are at increased risk. Branco et al. found that risk factors for fasciotomy following extremity trauma include presence of vascular injury, need for red blood cell transfusion, male gender, open fracture, elbow or knee dislocation, gunshot wound, injury severity score - 16, and age (1). Clinicians must maintain a high index of suspicion among patients at risk for developing acute compartment syndrome. The diagnosis is based on mechanism of injury, history, physical examination findings, and occasionally compartment pressures. Furthermore, following fasciotomy, the physician must anticipate common complications associated with fasciotomy, including infection, need for amputation, and technical complications including saphenous vein injury. Optimal timing of fasciotomy following injury has not been established. In one retrospective review of 88 patients undergoing fasciotomy following extremity trauma, it was suggested that fasciotomy within 12 hours of injury was associated with lower rates of infection. This study also showed no difference in rates of limb salvage or neurologic sequela when compared to patients receiving fasciotomy after 12 hours(2). In a later retrospective review of patients with lower extremity arterial trauma who underwent both open vascular repair and fasciotomies, Farber et al. found early fasciotomy (8 h from injury) was associated with a lower rate of amputation, infection, and length of stay when compared to patients who underwent later fasciotomy(3). Our aim is to establish is to build on this preliminary data with the use of a multi-center prospective observational trial in order to establish an optimal time window following injury for fasciotomy.

Study Design

Phase*
Not applicable

Design
Multi-center prospective observational trial

Study duration
2 years beginning from the time of IRB approval

Resources necessary for human research protection
Describe research staff and justify that the staff are adequate in number and qualifications to conduct the research. Describe how you will ensure that all staff assisting with the research are adequately informed about the protocol and their research related duties. Please allow adequate time for the researchers to conduct and complete the research. Please confirm that there are adequate facilities for the research.
Mark Seamon, MD is the principal investigator of this study. He is an attending trauma surgeon at the University of Pennsylvania. Jane Keating, MD is a co-investigator and the primary author of this IRB. She is a trauma fellow at the University of Pennsylvania. In addition to the staff at University of Pennsylvania, the other institutions involved will also have access to our Redcap survey in order to enter case information to accrue subjects. Adam Shiroff, MD is a co-investigator of the study. He is a trauma surgeon at University of Pennsylvania and performs and specializes in vascular and extremity trauma. His expertise will be valuable to the data analysis.

Characteristics of the Study Population

Target population
Trauma patients following blunt or traumatic extremity injury requiring revascularization

Subjects enrolled by Penn Researchers
25

Subjects enrolled by Collaborating Researchers
175

Accrual
We are a level one trauma center with a high volume of patients with extremity injury. This is a multicenter trial and will include other high volume level one trauma center.

Key inclusion criteria
-Trauma patients, both blunt and penetrating mechanisms -Patients with extremity injury requiring operative revascularization -Patients age greater or equal to15 years of age

Key exclusion criteria
-Patients age less than 15 years

Vulnerable Populations

	Children Form
	Pregnant women (if the study procedures may affect the condition of the pregnant woman or fetus) Form
	Fetuses and/or Neonates Form
	Prisoners Form
	Other
x	**None of the above populations are included in the research study**

The following documents are currently attached to this item:

There are no documents attached for this item.

Populations vulnerable to undue influence or coercion
None

Subject recruitment
All subjects will be recruited at the time of admission to the trauma bay or sometime during hospitalization when they meet enrollment criteria.

Will the recruitment plan propose to use any Penn media services (communications, marketing, etc.) for outreach via social media avenues (examples include: Facebook, Twitter, blogging, texting, etc.) or does the study team plan to directly use social media to recruit for the research?
No

The following documents are currently attached to this item:

There are no documents attached for this item.

Subject compensation*
Will subjects be financially compensated for their participation?
No

The following documents are currently attached to this item:

There are no documents attached for this item.

If there is subject compensation, provide the schedule for compensation per study visit or session and total amount for entire participation, either as text or separate document

None

Study Procedures

Suicidal Ideation and Behavior
Does this research qualify as a clinical investigation that will utilize a test article (ie- drug or biological) which may carry a potential for central nervous system (CNS) effect(s)?
No

Procedures
This is an observational study. Data will be collected by a provider questionnaire on REDchart following patient enrollment and hospitalization.

The following documents are currently attached to this item:

There are no documents attached for this item.

Deception
Does your project use deception?
No

International Research
Are you conducting research outside of the United States?
No

Analysis Plan
Risk factors for fasciotomy related complications will be assessed using univariate and multivariate analysis using Students t-test and the Mann Whitney U test. The Chi- squared tests or Fishers exact test will be used to compare categorical variables. Data will be reported as adjusted odds ratios with 95 % confidence intervals. Statistical significance will be set at a p value of less than 0.05.

The following documents are currently attached to this item:

There are no documents attached for this item.

Data confidentiality

	Paper-based records will be kept in a secure location and only be accessible to personnel involved in the study.
x	**Computer-based files will only be made available to personnel involved in the study through the use of access privileges and passwords.**
x	**Prior to access to any study-related information, personnel will be required to sign statements agreeing to protect the security and confidentiality of identifiable information.**
x	**Wherever feasible, identifiers will be removed from study-related information.**
	A Certificate of Confidentiality will be obtained, because the research could place the subject at risk of criminal or civil liability or cause damage to the subject's financial standing, employability, or liability.
	A waiver of documentation of consent is being requested, because the only link between the subject and the study would be the consent document and the primary risk is a breach of confidentiality. (This is not an option for FDA-regulated research.)
	Precautions are in place to ensure the data is secure by using passwords and encryption, because the research involves web-based surveys.
	Audio and/or video recordings will be transcribed and then destroyed to eliminate audible identification of subjects.

Subject Confidentiality
Patient data will be collected in an observational retrospective review. Other than patient medical record number and dates related to admission, procedures, discharge and/or death, no patient identifying information will be used, therefore ensuring subject confidentiality.

Sensitive Research Information*
Does this research involve collection of sensitive information about the subjects that should be excluded from the electronic medical record?
No

Subject Privacy
Privacy refers to the person's desire to control access of others to themselves. Privacy concerns people, whereas confidentiality concerns data. Describe the strategies to protect privacy giving consideration to the following: The degree to which privacy can be expected in the proposed research and the safeguards that will be put into place to respect those boundaries. The methods used to identify and contact potential participants. The settings in which an individual will be interacting with an investigator. The privacy guidelines developed by relevant professions, professional associations and scholarly disciplines (e.g., psychiatry, genetic counseling, oral history, anthropology, psychology).
Privacy will be maintained at all times to the best of the ability of the principal investigator and study personnel. Individuals wil not be interacting with investigators as this is an observational study.

Data Disclosure
Will the data be disclosed to anyone who is not listed under Personnel?
No

Data Protection*

	Name
	Street address, city, county, precinct, zip code, and equivalent geocodes
x	**All elements of dates (except year) for dates directly related to an individual and all ages over 89**
	Telephone and fax number
	Electronic mail addresses
	Social security numbers
x	**Medical record numbers**
	Health plan ID numbers
	Account numbers
	Certificate/license numbers
	Vehicle identifiers and serial numbers, including license plate numbers
	Device identifiers/serial numbers
	Web addresses (URLs)
	Internet IP addresses
	Biometric identifiers, incl. finger and voice prints
	Full face photographic images and any comparable images
	Any other unique identifying number, characteristic, or code
	None

Does your research request both a waiver of HIPAA authorization for collection of patient information and involve providing Protected Health Information ("PHI") that is classified as a "limited data set" (city/town/state/zip code, dates except year, ages less than 90 or aggregate report for over 90) to a recipient outside of the University of Pennsylvania covered entity?
No

Tissue Specimens Obtained as Part of Research*
Are Tissue Specimens being obtained for research?
No

Tissue Specimens - Collected during regular care*
Will tissue specimens be collected during regulator clinical care (for treatment or diagnosis)?
No

Tissue Specimens - otherwise discarded*
Would specimens otherwise be discarded?
No

Tissue Specimens - publicly available*
Will tissue specimens be publicly available?
No

Tissue Specimens - Collected as part of research protocol*
Will tissue specimens be collected as part of the research protocol?
No

Tissue Specimens - Banking of blood, tissue etc. for future use*
Does research involve banking of blood, tissue, etc. for future use?
No

Genetic testing
If genetic testing is involved, describe the nature of the tests, including if the testing is predicative or exploratory in nature. If predictive, please describe plan for disclosing results to subjects and provision

of genetic counseling. Describe how subject confidentiality will be protected Note: If no genetic testing is to be obtained, write: "Not applicable."
Not applicable

Consent

1. Consent Process

Overview
Informed consent will not be obtained given this is strictly an observational study, thus the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Children and Adolescents
Children and excluded from the study. Regarding adolescents, please see waiver of consent.

Adult Subjects Not Competent to Give Consent
Informed consent will not be obtained given this is strictly an observational study, thus the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

2. Waiver of Consent

Waiver or Alteration of Informed Consent*
Waiver of written documentation of informed consent: the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context

Minimal Risk*

Impact on Subject Rights and Welfare*

Waiver Essential to Research*

Additional Information to Subjects

Written Statement of Research*
No

If no written statement will be provided, please provide justificiation

Subjects are not consented and therefore do not statement of research. This is an observational study only.

The following documents are currently attached to this item:

There are no documents attached for this item.

Risk / Benefit

Potential Study Risks
The research involves minimal risk to the subjects, as it is strictly an observational study and does not alter the course of treatment in any way.

Potential Study Benefits
None

Alternatives to Participation (optional)

Data and Safety Monitoring
Principal investigator

The following documents are currently attached to this item:

There are no documents attached for this item.

Risk / Benefit Assessment
No benefit and no risk involved in this observational study

General Attachments

The following documents are currently attached to this item:

Cover Letter (irbcoverletter.docx)

HIPAA Authorization or Waiver (hipaawaiver1.docx)

Site Information (redcapsurveylink.docx)