

Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Protocol Number: H-48275
Status: Approved
Initial Submit Date: 11/18/2018
Approval Period: 12/10/2018 - 12/9/2019

Section Aa: Title & PI

A1. Main Title

POSTERIOR ANKLE ARTHROSCOPY IN PEDIATRIC POPULATION- INDICATIONS, MANAGEMENT AND OUTCOMES

A2. Principal Investigator

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A3a. Financial Conflict of Interest

Does any member of study personnel (Investigator (including Investigator's spouse and/or dependent children)) that are involved in the design, conduct, or reporting of the research have a Significant Financial Interest (SFI) that would reasonably appear to be affected by the research for which funding is sought and/or associated with an entity/business that would reasonably appear to be affected by the research?

No

Section Ab: General Information

A4. Co-Investigators

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A5. Funding Source:

Baylor College of Medicine (Internal Funding Only)

A6a. Institution(s) where work will be performed:

TCH: Texas Children's Hospital

A6b. Research conducted outside of the United States:

Country:
Facility/Institution:
Contact/Investigator:

Phone Number:

If documentation of assurances has not been sent to the Office of Research, please explain:

A7. Research Category:

A8. Therapeutic Intent

Does this trial have therapeutic intent?

No

Section B: Exempt Request

B. Exempt From IRB Review

Not Applicable

Section C: Background Information

Posterior ankle impingement (PAI) is a common cause of posterior ankle pain. PAI is usually aggravated excessive plantarflexion resulting in acute injury or simple overuse. [1, 2] Acute injuries associated with PAI are often result from the excessive plantarflexion or twisting predominately seen in soccer players, whereas, overuse injuries are often caused by repetitive plantarflexion often seen in dancers, gymnasts, and runners. [3,4,5,6,7] Patient populations who participant in such activities frequently and exaggerate plantarflexion motions of the angle may benefit from a procedure that reduces pain and also results in maximum range of motion. Open and arthroscopic techniques have been effective practices used to treat posterior impingement of the ankle and hindfoot. Arthroscopic intervention when compared to open procedure has included: decreased morbidity, reduced scarring and trauma to the surrounding tissues, and early rehabilitation, recovery, and return to daily and sporting activities. [8,9,10]

Ribbons et al found that complication rates for open procedures ranged from 7.0 % to 14%, with nerve injury at 4.2% and wound complication and infection rate at 2.8%. The same review reported an overall incidence of nerve injury at 3.7% and wound complication and infection rate of 0.96% for arthroscopic procedures. [1,2] Reduction of return to sport time also improved in patients receiving arthroscopic procedures versus open procedures; arthroscopic procedures average only 8.9 weeks whereas open procedures average a return to sport time of 14.8 weeks to return to sporting activities.

We believe that this will be the first prospective outcome study on posterior impingement that will include outcome measures and indications in a pediatric population. Previous studies have focused on posterior impingement but in a primary adult population.

Section D: Purpose and Objectives

This study will establish a database of prospectively identified patients undergoing posterior ankle arthroscopy in a pediatric population and collect information regarding their presentation, previous illness, treatment, and outcomes in the course of receiving currently available treatments.

We hypothesized that arthroscopic treatment of posterior impingement would be associated with significant improvements in pain and functions, restoration of motions, a lower complication rates.

Section E: Protocol Risks/Subjects

E1. Risk Category

Category 1: Research not involving greater than minimum risk.

E2. Subjects

Gender:

Both

Age:

Adolescent (13-17 yrs), Adult (18-64 yrs), Child (3-12 yrs)

Ethnicity:

All Ethnicities

Primary Language:
English, Spanish

Groups to be recruited will include:
Patients

Which if any of the following vulnerable populations will be recruited as subjects?
Children

Vulnerable populations require special protections. How will you obtain informed consent, protect subject confidentiality, and prevent undue coercion?

The investigator and/or research coordinator will review patient eligibility, if eligible, the parent / legal guardian and or subject will be approached for possible enrollment in the study. Consent will be obtained from the parent and from the child using the child clause in the consent document. Participants and their family members will have adequate time to ask questions and discuss with each other to prevent coercion. Informed consent will be obtained after a full explanation of the study is completed and all questions answered.

E3. Pregnant woman/fetus

Will pregnant women and/or fetuses (as described in 45 CFR 46 Subpart B) be enrolled in the research?
No

E4. Neonates

Will neonates of uncertain viability or nonviable neonates (as described in 45 CFR 46 Subpart B) be enrolled in the research?
No

E5. Children

Will children be enrolled in the research?
Yes

Section F: Design/Procedure

F1. Design

Select one category that most adequately describes your research:
g) Data repository (database or registry)

Discuss the research design including but not limited to such issues as: probability of group assignment, potential for subject to be randomized to placebo group, use of control subjects, etc.

The present study will be established as database of prospectively identified patients undergoing posterior ankle arthroscopy meeting study inclusion criteria. Therefore, the study will continue to enroll and follow patients as long as there is the necessary administrative infrastructure to support the existence and maintenance of the registry. Patient enrollment will continue for a minimum of 5 years. All enrolled patients, will be followed for a minimum of 1 year post intervention. The patients and parents will be told and it will be stated in the consent that data collected up to 1 year or more after the intervention will be used for research study purpose.

Inclusion Criteria:

All patients undergoing posterior ankle arthroscopy at Texas Children's Hospital greater than 2 through 18 years of age. The expected age range for this study population will be 8 to 18 years of age .

Exclusion Criteria:

All patients undergoing posterior ankle arthroscopy 19 and older age will be excluded.

F2. Procedure

The present study will be established as database of prospectively identified patients undergoing posterior ankle arthroscopy meeting study inclusion criteria.

Each consented participant for the study will be followed regularly as part of standard of care. A review of medical records may be required to determine preliminary eligibility according to inclusion and exclusion criteria. Subject informed consent and assent (when reasonable) must be signed for study participation.

Data Collection: All patients will undergo standard of care only; diagnostic tests or imaging for the sole purpose of research will not be performed. The following data will be collected for patients included in this study (please refer to data collection

forms attached in Section S). Patient data will be collected up to 1 year or more after the intervention and will be used for research purposes.

The data collection schedule as follows: Treatment, follow- up visits (1-2 weeks, 1 month, 3 months, 6 months, and 12 months).

At each visit the following information will be collected: 1. Study subject's history and clinical findings. 2. Treatment and outcomes in the course of receiving standard-of-care treatment. 3. VAS pain scale (Current Pain level). 4. AOFAS Ankle Hindfoot Score, and X-rays (as needed based on standard of care).

Other investigators cannot withdraw data for their separate research.

Section G: Sample Size/Data Analysis

G1. Sample Size

How many subjects (or specimens, or charts) will be used in this study?

Local: 50 Worldwide: 50

Please indicate why you chose the sample size proposed:

We chose this sample size because regionally/locally orthopedic teams treat approximately 15-20 patients within a 2 years. Since only one provider at TCH treats this condition within children we believe that our sample size would be approximately the same within a minimum of 5 years of enrollment. Since this is an "open ended" registry, we believe that we will have similar numbers to other regional and local pediatric orthopedic teams/hospitals with this patient population. Since recruitment begun, we have seen an increase in the number of patients treated with this condition. Therefore we project our sample size to be greater than 20 patients previous seen in our population.

G2. Data Analysis

Provide a description of your plan for data analysis. State the types of comparisons you plan (e.g. comparison of means, comparison of proportions, regressions, analysis of variance). Which is the PRIMARY comparison/analysis? How will the analyses proposed relate to the primary purposes of your study?

This research study is purely observational and is conducted more like a patient registry and data repository than a formal clinical trial. Therefore, the study will continue to enroll and follow patients as long as there is the necessary administrative infrastructure to support the existence and maintenance of the registry. A TCH statistician will analyze the data. A multivariable logistic regression model will be used to assess risk factors and categorical parameters will be compared using Fisher's exact test or Chi-square test. For continuous variables, a summary of the means and standard deviations will be conducted and compared using a t-test or a Wilcoxon rank test.

Section H: Potential Risks/Discomforts

H1. Potential Risks/Discomforts

Describe and assess any potential risks/discomforts; (physical, psychological, social, legal, or other) and assess the likelihood and seriousness of such risks:

A possible risk to patients would be loss of confidentiality; however, this risk is reasonable in relation to the anticipated benefits to patients and is in relation to the intellectual importance that may be gained from this study.

There is a risk of violation of patient privacy but steps will be taken to mitigate this risk. Prior to entering data into the research database, patient will be consented and then assigned a study identifier (code) that replaces his/her name and medical record number. EPIC will be used to capture and store research information including radiographic and MR imaging studies, clinical information, and patient and/or outcomes questionnaire responses. The data will be de-identified prior to transferring to the research database. The database server will be maintained behind a firewall at the Texas Children's Hospital.

H2. Data and safety monitoring plan

Do the study activities impart greater than minimal risk to subjects?

No

H3. Coordination of information among sites for multi-site research

Is the BCM Principal Investigator acting as the SPONSOR-INVESTIGATOR for this multi-site research?

No or Not Applicable

Is BCM the COORDINATING CENTER for this multi-site research?

No or Not Applicable

Section I: Potential Benefits

Describe potential benefit(s) to be gained by the individual subject as a result of participating in the planned work.

There are no direct benefits to the participating patients. Benefits to society is the scientific contribution to the medical community and the public.

Describe potential benefit(s) to society of the planned work.

The patient's contribution will provide information that can potentially improve the evaluation, treatment, and surgical outcome of patients undergoing posterior ankle arthroscopy. T

Do anticipated benefits outweigh potential risks? Discuss the risk-to-benefit ratio.

The minimal risks to patients (i.e. loss of confidentiality) are reasonable in relation to the anticipated benefits to patients and are in relation to the intellectual importance that may be gained from this study.

Section J: Consent Procedures

J1. Waiver of Consent

Will any portion of this research require a waiver of consent and authorization?

No

J1a. Waiver of requirement for written documentation of Consent

Will this research require a waiver of the requirement for written documentation of informed consent?

No

J2. Consent Procedures

Who will recruit subjects for this study?

PI

PI's staff

Describe how research population will be identified, recruitment procedures, any waiting period between informing the prospective participant and obtaining consent, steps taken to minimize the possibility of coercion or undue influence and consent procedures in detail.

Patients will be identified by the treating orthopedic surgeon(s). Potential study participants meeting the inclusion criteria will be identified from the Texas Children's Hospital Orthopedic Clinics by the treating physicians and research staff. This may require a chart review to determine patient's eligibility. The chart review will include review of history and physical and age at diagnosis and prior treatment. All potential subjects are patients of the Principal Investigator or Co- investigators. The patients and parents will be told and it will be stated in the consent that data collected up to 1 year or more after the intervention will be used for research study purpose.

The surgeon and / or research staff will approach the patient and parent(s) or legal guardian(s) at the time of routine clinic visit that a study is being conducted to determine the results of current treatments for patients undergoing posterior ankle arthroscopy. The surgeon and/or research staff will inform the patient and parent(s) or legal guardian(s) that participation or non-participation will not influence treatment options. Patient and/or parent will be informed that the patient's medical information and information collected will be placed in a secure computer database. The data will be coded after being collected for the purpose of this study. The research coordinator will offer the patient and parent(s) or legal guardian(s) the opportunity to take materials with them for further review prior to consenting. A child age 11 to 18 will provide his or her own assent if they are mentally capable to comprehend the purpose and procedure. The "child clause" on the consent form will be utilized for patient assent. A waiver of assent has been requested for patients 6-10 years of age and those without the mental capability to comprehend the purpose and procedure. The person obtaining informed consent will record documentation of the recruitment process, invitation to participate in the study, and informed consent. For families who we would like to consent that are non-English speaking patients a short form in Spanish will be utilized for Spanish speaking patients and a translator will be present during the consent process.

Are foreign language consent forms required for this protocol?

Yes

Which of the following ways will you document informed consent in languages other than English?

Short-Form consent documents

J3. Privacy and Intrusiveness

Will the research involve observation or intrusion in situations where the subjects would normally have an expectation of privacy?

No

J4. Children

Will children be enrolled in the research?

Yes

J5. Neonates

Will non-viable neonates or neonates of uncertain viability be involved in research?

No

J6. Consent Capacity - Adults who lack capacity

Will Adult subjects who lack the capacity to give informed consent be enrolled in the research?

No

J7. Prisoners

Will Prisoners be enrolled in the research?

No

Section K: Research Related Health Information and Confidentiality

Will research data include identifiable subject information?

Yes

Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.

Yes

Specific information concerning alcohol abuse:

No

Specific information concerning drug abuse:

No

Specific information concerning sickle cell anemia:

No

Specific information concerning HIV:

No

Specific information concerning psychiatry notes:

No

Demographic information (name, D.O.B., age, gender, race, etc.):

Yes

Full Social Security #:

No

Partial Social Security # (Last four digits):

No

Billing or financial records:

No

Photographs, videotapes, and/or audiotapes of you:

No

Other:

No

At what institution will the physical research data be kept?

The physical PHI research data will be contained at Texas Children's Hospital (TCH) within the Orthopedic Surgery and Scoliosis Department.

How will such physical research data be secured?

All data will be stored in a secure manner (locked filing cabinets) and closely monitored at all times. Each participant will

be identified using only an assigned participant identification number and the participant identification key list will be stored in a separate secure and password protected file. Only personnel associated with this study will have access to the data. All consent documentation will be stored on site in electronic and/or hard copy form.

At what institution will the electronic research data be kept?

Data will be collected prospectively and entered into EPIC (Electronic Privacy Information Center), electronic health records software. Data will be entered into the medical charts using Posterior Ankle flow sheet developed for this study to record patient data. Prior to data analysis, data will be de-identified and exported to secured, password protected computer spreadsheets on the TCH server. This database will be kept at Texas Children's Hospital, research staff at TCH will have a user name and password to log in and enter coded subjects into the database. Each participant will be identified using only assigned participant identification number and the participant key list will be stored in a separate password protected file. Only personnel associated with this study will have access to the data.

Such electronic research data will be secured via BCM IT Services- provided secured network storage of electronic research data (Non-Portable devices only):

No

Such electronic research data will be secured via Other:

Yes, (describe below):

All data will be stored in a secure manner (locked filing cabinets) and closely monitored at all times on the an encrypt TCH server. Each participant will be identified using only an assigned participant identification number and the participant identification key list will be stored in a separate secure and password protected file. Only personnel associated with this study will have access to the data.

Will there be anyone besides the PI, the study staff, the IRB and the sponsor, who will have access to identifiable research data?

No

Please describe the methods of transmission of any research data (including PHI, sensitive, and non-sensitive data) to sponsors and/or collaborators.

There are no sponsors and/or collaborators associated with this study.

Will you obtain a Certificate of Confidentiality for this study?

No

Please further discuss any potential confidentiality issues related to this study.

We do not anticipate any other confidentiality issues related to this study.

Section L: Cost/Payment

Delineate clinical procedures from research procedures. Will subject's insurance (or subject) be responsible for research related costs? If so state for which items subject's insurance (or subject) will be responsible (surgery, device, drugs, etc). If appropriate, discuss the availability of financial counseling.

There is no extra cost to the patient if they participate in this study. Procedures that are considered standard of care will be billed to their insurance provider as they normally would.

If subjects will be paid (money, gift certificates, coupons, etc.) to participate in this research project, please note the total dollar amount (or dollar value amount) and distribution plan (one payment, pro-rated payment, paid upon completion, etc) of the payment.

Dollar Amount:

0

Distribution Plan:

Subjects will not be paid for their participation in the study.

Section M: Genetics

How would you classify your genetic study?

Discuss the potential for psychological, social, and/or physical harm subsequent to participation in this research. Please discuss, considering the following areas: risks to privacy, confidentiality, insurability, employability, immigration status, paternity status, educational opportunities, or social stigma.

Will subjects be offered any type of genetic education or counseling, and if so, who will provide the education or counseling and under what conditions will it be provided? If there is the possibility that a family's pedigree will be presented or published, please describe how you will protect family member's confidentiality?

Section N: Sample Collection

None

Section O: Drug Studies

Does the research involve the use of ANY drug* or biologic? (*A drug is defined as any substance that is used to elicit a pharmacologic or physiologic response whether it is for treatment or diagnostic purposes)

No

Does the research involve the use of ANY gene transfer agent for human gene transfer research?

No

O1. Current Drugs

Is this study placebo-controlled?

No

Will the research involve a radioactive drug that is not approved by the FDA?

No

Section P: Device Studies

Does this research study involve the use of ANY device?

No

Section Q: Consent Form(s)

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Section R: Advertisements

None