A Randomized, Control Clinical Trial: The Effect of Different Injection Regimens of Autologous Conditioned Plasma for the Treatment of Symptomatic Knee Osteoarthritis

Date: 06/27/2019
NCT03889925

RESEARCH SUBJECT INFORMATION, CONSENT FORM, AND HIPAA AUTHORIZATION FOR RESEARCH

TITLE OF PROJECT: A Randomized, Control Clinical Trial: The Effect of Different Injection Regimens of Autologous Conditioned Plasma for the Treatment of Symptomatic Knee Osteoarthritis

INVESTIGATOR: Adam Anz, M.D.
Andrews Institute

CO-INVESTIGATOR: Roger Ostrander, M.D.
Steve Jordan, M.D.
Christopher O'Grady, M.D.
Brett Kindle, M.D.
Hillary Plummer, PhD, ATC

SITE(S): Andrews Research & Education Foundation (AREF)

SPONSOR: In-House

INVESTIGATOR CONTACT INFORMATION:

Andrews Institute
1040 Gulf Breeze Pkwy
Gulf Breeze, FL 32561
(850) 916-8796

Informed Consent Document
A Randomized, Control Clinical Trial: The Effect of Different Injection Regimens of Autologous Conditioned Plasma for the Treatment of Symptomatic Knee Osteoarthritis

INTRODUCTION:
In order to decide whether you wish to participate in this research study, you should understand why the study is being done, how the study will be run, the types of study procedures involved, your time commitments, and the possible risks and/or benefits associated with your participation to enable you to make an informed decision. This process is known as "informed consent."

This written consent form and HIPAA Authorization provides detailed information about the research study. This consent form and HIPAA Authorization may contain words that you do not understand. Please ask the study doctor ("Investigator" or "Researcher") or the study staff to explain any words or information that you do not clearly understand. Before you decide to take part in this study, you may want to think about it more, or discuss it with family or friends. You can take a copy of this form home with you before making your decision. Your participation in this study is voluntary. You should not join this research study until all of your questions are answered to your satisfaction.

If you wish to participate in this research study, you will be asked to sign this consent form and HIPAA Authorization. You must sign before any study procedures are done. You will be given a copy of this consent form and HIPAA Authorization to keep for your records.

PURPOSE OF THE RESEARCH STUDY:
You are being asked to participate in research being conducted by the Andrews Institute. The purpose of this study is to determine if hyaluronic acid injected at the same time as autologous conditioned plasma (ACP), a platelet rich plasma product, will improve the performance of ACP in the treatment of symptomatic knee osteoarthritis.

SELECTION OF SUBJECTS:
If you decide to be in this study, you will be one of 80 people in this research study. You must be between the ages of 30 and 80 and have documented radiographic evidence of OA in the knee. You must have a documented diagnosis of primary OA for at least 6 weeks. If you have had viscosupplementation in the involved knee in the past 6 months you will not be able to participate. If you have had a corticosteroid injection in any joint within 3-months prior to screening you will be excluded. If you have gout or rheumatologic disease or a previous negative experience with HA you will be excluded from participating. If you will have difficulty obtaining internet access, do not have an active e-mail address, or are unable to comprehend study documents or give informed consent you will be excluded. You are being recruited for participation in this study because your doctor thinks your knee pain will be improved with a series of injections.

RESEARCH PROCEDURES:
If you agree to be in the study, we will ask you to do the following things:

You will complete patient reported outcome questionnaires prior to your injection. The questionnaires will ask you about your knee pain and function and will take approximately 20 minutes to complete. You will then be randomly assigned to receive an injection of autologous conditioned plasma either with or without hyaluronic acid. A trained medical professional will then draw blood from your arm and use a special machine to spin the blood into autologous conditioned plasma. This autologous conditioned plasma product will then be injected by your doctor into your knee joint. The same procedures will be repeated once a week for two additional weeks. You will receive 3 injections total over a 3-week period of time. If you are assigned to the group who gets autologous conditioned plasma with hyaluronic acid, you will receive two injections of autologous conditioned plasma and hyaluronic acid once a week for 2-weeks and a third injection on the third week of only autologous conditioned plasma. You will complete the questionnaires at 1, 3, 6, 12, 18, and 24 months after the final injection.

RISKS AND DISCOMFORTS:
The following risks may be associated with your participation in this study. Potential risks include those expected with any injection including syncope, dizziness, headache, nausea, tachycardia, infection (septic arthritis, phlebitis, and osteomyelitis), bleeding, or pain. Additionally, you may experience knee stiffness or inflammation associated with the procedures. These risks would not be any higher with the test interventions than those patients are subject to with injection treatments of knee osteoarthritis. As with any research involving patients there is the inherent risk of a breach in patient confidentiality though this will be minimized through the use of participant code numbers and adherence to all HIPAA guidelines.

There is a small risk of disclosure of your protected health information, which will be minimized where possible, including the removal of all identifiable information from data collection sheets and storing study information in secure locations as described in more detail below.

ALTERNATIVES:
You do not have to take part in this study and can choose to proceed without receiving injections to treat your symptoms of knee osteoarthritis. Alternative treatment options include activity modification and physical therapy.

BENEFITS:
The following benefits may be associated with your participation in this study: include injections that may provide potential pain relief, improvement of knee function, and improvement of quality of life, which all could lead to the avoidance of surgical intervention.

CONFIDENTIALITY:
All personal information is strictly confidential, and no names will be disclosed except as required by law. Your individual performance or results will not be reported; when/if this study is published, only

the results of all participants as a group will be reported. During the course of this study, your information will be de-identified and identified only by a subject number.

All information and data collected during this research will be recorded in a spreadsheet. This spreadsheet will not contain protected health information. The spreadsheet will be stored in a secure password protected folder on a laptop that only the study Investigators will have access to and will be permanently deleted following publication of any and all manuscripts, if any, written as a result of this research. Records related to this study will be securely retained in a secure location for a period of 3 years after the completion of the study or longer as required by law. At that time, all records will be properly destroyed.

HIPAA and PROTECTED HEALTH INFORMATION:

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

You are being asked to sign this authorization allowing us to share your PHI for purposes of this research study. If you sign this authorization, you give permission to the Investigators to use or disclose your PHI for the research study described here. You can decide to sign or not to sign this authorization. However, if you choose not to sign this authorization, you will not be able to take part in the research study. Whatever choice you make, it will not have an effect on your access to medical care.

The United States government has issued a privacy rule to protect the privacy rights of patients ("Privacy Rule"). This rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Privacy Rule is designed to protect the confidentiality of your health information. Andrews Research and Education Foundation is required by law to protect your health information. By signing this document, you authorize Andrews Research and Education Foundation to use and/or disclose your health information for this research. Those persons who receive your PHI may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

During this study, the Investigators will need to use your PHI. PHI is information about you that could be used to identify you, such as your name, address, telephone number, date of birth, new and existing medical records, or the types, dates, and results of various tests and procedures. This may also include information in your medical record and information created or collected during the study. We may also ask other health care providers to give us any information about your health status or your health care. If you sign this authorization, you are agreeing to allow the Researchers to use your PHI to carry out this study.

By signing this authorization, and solely for the purposes of completing this research, you also allow the research staff to disclose your PHI to outside entities involved in completing the research project, such as people who review the research study, their staff, lawyers, government groups (such as the Food and Drug Administration), or safety monitors. The study data that the Researchers send to these entities will not include your name, address, or social security number, but instead, will be designated with a code number. However, your medical records can be reviewed or copied at the study site by regulatory authorities or other oversight bodies, including the Institutional Review Board. The purpose of these reviews is to make sure the study is being conducted properly and that the data is being collected correctly, or for other purposes allowed by law.

Your PHI may no longer be protected by the privacy rule once it is disclosed. Your PHI will be kept as confidential as possible under the law; however, absolute confidentiality cannot be guaranteed.

You may cancel this authorization at any time by writing to the Investigator at the Contact Information provided above. If you cancel this authorization, the Researchers will no longer use or disclose your PHI under this authorization for this study, unless it is needed to preserve the scientific integrity of the study. Information obtained before you cancel the authorization may still be used by the Researchers. If you do not cancel this authorization, it will automatically expire at the conclusion of the research study.

COST AND COMPENSATION:

There will be no cost to you for participating and you will not receive any compensation for participating in this research. In the unlikely event of an emergency, AREF will provide basic first aid medical treatment. However, if you were to require additional medical care as a result of participating in this study, you would need to contact your personal physician at your own expense.

The Investigators, the employers of the Investigators, and the Research Site do not have programs for compensating subjects for injury or complications related to human subjects research. Any treatment will be at your expense.

VOLUNTARY PARTICIPATION/WITHDRAWAL:

Taking part in this study is voluntary. Your medical treatment, costs of treatment and eligibility for benefits will not be affected if you decide not to sign this Consent Form or participate in the study. If you agree to participate, in the event new information becomes available that may affect your willingness to participate in this study, this information will be given to you so that you can make an informed decision about whether or not to continue your participation.

QUESTIONS:

It is your right, as a research participant, to ask questions at any time regarding the procedures involved and any aspects of this study including the potential benefits or risks. For any questions you may have for the Investigators, you may contact them at (850) 916-8796.

If you have questions about your rights as a research subject or if you have questions, concerns or complaints about the research, you may contact the Baptist Hospital Institutional Review Board* at (850) 469-2227. The IRB will not be able to answer some types of questions, such as questions about appointment times.
*The IRB is a group of individuals who independently review research

STATEMENT OF CONSENT TO PARTICIPATE IN THIS RESEARCH STUDY:
By signing this consent form I agree to and acknowledge the following statements:

I agree to participate as a subject with the understanding that my participation is completely voluntary, and that I may withdraw at any time without prejudice by sending a written request to the Investigator at the Sports Medicine Research Lab, Andrews Research and Education Foundation, 1020 Gulf Breeze Pkwy, Gulf Breeze, FL 32561.

I have read and understand the above information and have been given the opportunity to discuss it and ask questions.

I understand that this authorization does not have an expiration date.

I have received a copy of this authorization form for my records.

I have been informed that I may contact the Investigators by phone at (850) 916-8796 in order to answer any questions that I may have at any time during my participation.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

_____ _____
Signature of Person Conducting Informed Consent and HIPAA Authorization Discussion Date