RUSH

ECONSENT/AUTHORIZATION FOR PARTICIPATION IN A RESEARCH STUDY

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Protocol Title: Prospective, Double Blind, Randomized Control Trial Comparing the Efficacy of Intra-articular Injections for the Treatment of Primary Glenohumeral Osteoarthritis

Sponsor: Department of Orthopedics

Key Information:

You are being invited to participate in a research study. Research studies answer important questions that might help change or improve the way we do things in the future.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

Taking part in this research study is voluntary. You do not have to participate in this study and may choose to leave the study at any time. If you decide not to participate in this study or leave the study at a later time, your health care, benefits, or relationship with Rush University Medical Center will not change or be affected.

The purpose of this study is to investigate whether Platelet Rich Plasma (PRP) injections or corticosteroid (steroid) injections can lead to any improvement in symptoms in participants experiencing shoulder osteoarthritis. PRP comes from a small sample of your own blood which is then processed using a device to separate the components of your blood to have a higher number of platelets than normal. Platelets are the part of your blood that helps with clotting. They release growth factors that may have a direct effect on healing certain tissues and reducing inflammation or pain. PRP is normally injected into injured tendons, ligaments, and soft tissue. PRP injections have shown some benefit for knee osteoarthritis, but the effects on shoulder osteoarthritis is also unknown. PRP injections for shoulder osteoarthritis are considered an off-label (non-approved) use. This means it is not an established treatment for this condition. The steroid, methylprednisolone, is approved by the Food and Drug Administration (FDA) for injection into joints and is commonly used in the treatment of osteoarthritis, but is not specifically approved for use in the shoulder

If you agree to participate in this study, your participation may last up to 1 year. You will not be required to return to the office for follow-up visits. You will be asked to complete questionnaires

at specific times during the course of the study.

There are risks to you for participating in this study. In this study, there is a risk of there is a risk of loss of confidentiality if your medical information or your identity is obtained by someone other than the investigators, but precautions will be taken to prevent this from happening. For a detailed description of risks you should know about, please see the "*What are the risks and discomforts of participating in this study?*" section of this consent form.

You may benefit from taking part in this study. Based on experience with PRP and steroid injections in patients with knee osteoarthritis, researchers believe either injection may be of some benefit to people with shoulder joint (glenohumeral) osteoarthritis, or it may be as good as standard therapy with fewer side effects. However, because people respond differently, no one can know in advance if it will be helpful for you.

There are other options available to you if you decide not to participate in this study. You may choose another form of treatment or care for your shoulder joint osteoarthritis without being in a study such as steroid shoulder injections or paying out of pocket for PRP injections. The study doctor or research coordinator will discuss these choices with you. You do not have to participate in this study to be treated for shoulder joint osteoarthritis.

Detailed Information: Please review the rest of this document for details about the above topics and additional information you should know before making a decision about whether or not you will participate in this study.

Why are you being invited to participate in this study?

You are being asked to participate in this study because you have been diagnosed with glenohumeral (shoulder joint) osteoarthritis, and you have not had a surgery on that shoulder in the past year, or an injection in that shoulder in the last 3 months. In order to be eligible for this study you must have had a prior shoulder X-ray showing glenohumeral osteoarthritis. X-rays will not be performed as part of this study.

How many participants will take part in this study?

Approximately 200 participants are expected to take part in this study.

What are the activities you will be doing if you participate in this study?

If you agree to be in this study, you will be asked to participate in the following activities (also outlined in the table below):

- **Randomization**: Once enrolled in the study, you will be randomly assigned (by chance, like the flip of a coin) into one of two treatment groups for a single shoulder injection: Platelet Rich Plasma (PRP) or Steroid (methylprednisolone and lidocaine). Lidocaine is an anesthetic (numbing medicine) used to prevent irritation from the steroid injection. You will be blinded during the duration of the study follow up period of 52 weeks after the injection. Blinded means that neither you nor the provider (study doctor) will know which treatment group you are assigned to until the observation period is over (52 weeks).

- **Blood draws**: Regardless of the group that you are randomized to, 15 mL (about 3 teaspoons) of blood will be drawn from your arm before your shoulder injection. If you are assigned to the PRP injection group, your blood will be drawn and processed for 5 minutes to create the PRP injection using a device called the Arthrex Autologous Conditioned Plasma kit. In order to maintain the blinding, all participants regardless of the treatment group will have 15 mL of blood drawn and a 5 minute waiting period to simulate the normal PRP processing time. All injection syringes will be covered with finger cots or tape to blind both the participant and provider to the type of injection being administered. Ultrasound-guidance will be used to confirm the location of the intra-articular injection in the shoulder.
- **Surveys** (outlined in the table below): You will also be asked to complete the Patient Reported Outcomes Measure (PROM) surveys which include: Visual Analog Scale-Pain (VAS), American Shoulder and Elbow Surgeons (ASES), Single Assessment Numeric Evaluation (SANE), Constant, QuickDASH, and Veterans Rand/Short-Form 12 (VR/SF-12) to evaluate the outcome after the injection. These surveys can be completed remotely and will be sent securely to an email address you provide. The surveys that are sent at each time point take approximately 10-15 minutes. PROMs will be completed prior to injection and at 6, 12, 24, and 52 weeks post-injection.

Event	**Day of Injection**	**Post-injection Week**			
		6	12	24	52
Informed Consent	X				
Demographic Collection: such as age, race, sex, occupation, education	X				
Confirm Inclusion/Exclusion Criteria (requirements)	X				
Randomization	X				
Injection	X				
Questionnaires (ASES, SANE, Constant, VAS, VR/SF-12, QuickDASH)	X	X	X	X	X

Will you be contacted about participating in future research?

By participating in this research, we are assuming that we may contact you after your participation in this study about participating in other research studies. If this is not the case please inform the study staff or email Carla Edwards, PhD at Carla_edwards@rush.edu.

What are the risks and discomforts of participating in this study?
Taking part in this study may expose you to risks.

In this study, there is a risk of there is a risk of loss of confidentiality if your medical information or your identity is obtained by someone other than the investigators, but precautions will be taken to prevent this from happening.

Some people may experience side effects or discomfort, some of which may be serious. It is very important that you understand the known risks in this research study before you decide whether to participate. Side effects, risks, and/or discomforts from participation are grouped by the different aspects of the study:

Risks for the blood draw for lab tests: may include pain, bruising, bleeding and/or swelling at the puncture site, light-headedness or fainting, and, on rare occasions, infection.

The known risks and complications of the injection procedure to deliver the steroid or PRP to your shoulder include: bleeding, bruising, infection, injury to nerves or vessels, joint warmth, joint stiffness or swelling, or persistent pain or not obtaining full shoulder function.

Side effects of steroid injections include: thinning of skin or nearby bone, and changes in skin color around the injection site and allergic reaction. Risks of the lidocaine included in the injection include allergic reactions. Please inform the study staff of all known allergies, especially if you have ever had a reaction to an anesthetic (numbing medication). **All participants will be asked if they have an allergy to lidocaine as part of screening during the study. Any participants who have an allergy to lidocaine will be excluded from the study.**
Questionnaires: Some of the questions on the quality of life questionnaires ask the subject to consider areas of their life which they may not commonly think about. There are no physical risks from completing the survey, but the questions could cause concern or possibly emotional distress.

It is also not known if you receive any benefit from one of the study injections, how long the benefits of the injection will last, and whether there will be a difference in the duration of response between the study groups.

There may be other risks that may happen that we cannot predict.
What are the reproductive risks of participating in this study?
There may be other risks that may happen that we cannot predict. If you are pregnant you cannot be a part of this study. If you suspect you may be pregnant please inform your doctor and you will not be asked to participate. Pregnancy testing will not be offered by this study.

What if there is new information that may affect your decision to participate in this study?
During this study, you will be told about important findings (either good or bad), such as changes in the risks or benefits of participation in the study or new choices to participation that might cause you to change your mind about being in the study. If new information is shared with you, you may be asked to sign a revised consent form in order to continue participating in this study.

Will you receive your individual results from the study?
Generally, activities performed for research purposes are not meant to provide clinical information. We may learn things about you from this study which could be important to your health or treatment. However, we will not share these results with you because his is a research study and not a clinical treatment.

Can you leave or be removed from this study?
You have the right to leave a study at any time without penalty. For your safety, however, you should consider the study doctor's advice about how to leave this study. If you leave this study before the final study visit, the study doctor may ask you to complete the final steps.

The researchers and Sponsor also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interests;
- You do not follow the instructions;
- The study is cancelled for any reason.

What about confidentiality of your medical information?
This authorization is voluntary. Rush University Medical Center and its affiliates ("Rush") will not withhold or refuse your treatment, payment, enrollment, or eligibility for benefits if you do not sign this authorization. You do not have to sign this authorization, but that means that you cannot be in the study or receive study-related treatment.

By signing this document, you voluntarily authorize (give permission to) Dr. Yanke his study team, and other Rush personnel involved with the conduct and review of this study (which may include off-site personnel) to use or disclose (release) health information that identifies you for the study described in this document.

During the study, Dr. Yanke his study team study team will collect Protected Health Information (PHI) about you for the purposes of this research. PHI is your health information that includes your medical history and new information obtained as a result of this study. Some of this information will come from your medical record. The health information that Rush may use or disclose for this research includes information already in your medical record (medical history, physical exam), as well as information created or collected during the study (blood test results). The study doctor will use this information about you to complete this research

Dr. Yanke his study team study team may share your health information and the results of your study-related procedures and tests with people outside of Rush who assist with the conduct and review of this study. The persons who receive your health information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, but only if permitted by the laws governing them. Your health information described above may be used or disclosed to the:

- Researchers and study team at Rush;

- Rush Department of Orthopedics, and Midwest Orthopaedics at Rush
- Monitoring agencies such as the Food and Drug Administration (FDA), the National Institutes of Health and the Rush Institutional Review Board (IRB).

While you participate in the study you will have access to your medical record, but Dr. Yanke is not required to release to you study information that is not part of your medical record. Rush is required by law to protect your health information, and study records that identify you will be kept confidential. The results of study tests/procedures performed as part of this study may become part of your medical record. Any study information in your medical record will be kept indefinitely. Your identity will not be revealed on any report, publication, or at scientific meetings.

You have a right to inspect and copy the information to be disclosed with this authorization and you may obtain a copy of the information by contacting the office listed below.

If you no longer want to be in the study and do not want your future health information to be used, you may change your mind and revoke (take back) this authorization at any time by writing to Dr.Yanke at 1611 W. Harrison Street, Suite 300 Chicago, IL 60612. If the authorization is revoked, you will no longer be allowed to participate in the study and previously authorized individuals/entities may still use or disclose health information that they have already obtained about you as necessary to maintain the integrity or reliability of the current study.

This authorization is valid for the entirety of this research study. It will expire upon completion of the study or if you revoke (take back) the authorization.

If you withdraw from this study, the data already collected from you may not be removed from the study records. The study doctor and/or study team may ask you whether they can continue to collect follow-up data on you. If follow-up information will be requested, you will be asked to sign a separate consent form before this information can be collected.

Records of participation in this study will be maintained and kept confidential as required by law. Study documents will be kept in a secured location on site. Electronic study data will be kept in and encrypted, secured database at the study site.

The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews new and ongoing human research studies to check that the rules and regulations are followed regarding the protection of the rights and welfare of human participants. 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.

What are the costs to participate in this study?

There are no costs to you for participating in this research study. All costs for the study (including shoulder injection, PRP blood tests, and blood draw) will be paid by the Department of Orthopedics.

Will you be paid for your participation in this study?
You will not be paid for being in this study.

What if you are injured as a result of your participation in this study?
If you get ill or injured from being in the study, Rush University Medical Center will help you get medical treatment. You should let the study doctor know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact Dr. Yanke at telephone number (312) 563-2880.

You should let any health care provider who treats you know that you are in a research study. If you do seek medical treatment, please take a copy of this document with you because it may help the doctors where you seek treatment to treat you. It will also provide the doctors where you seek treatment with information they may need if they want to contact your study doctor.

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You or your health insurance plan will be billed. No money has been set aside to pay the costs of this treatment. Health insurance plans may or may not cover costs of research-related injury or illness. You should check with your insurance company before deciding to participate in this research study. The study staff will assist you in obtaining pre-authorization from your insurance company. Costs not covered by insurance could be substantial.

Rush University Medical Center has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study.
By signing this form, you are not giving up any legal rights to seek compensation of injury.

What other information should you know about?

Investigator Dual-Role
Your health care provider is an investigator on this research study, and as an investigator, is interested in both your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may ask for a second opinion about your care from a clinician who is not associated with this study. You are not obligated to participate in any research study offered by your clinician. The decision to not participate will not affect your clinical care now or in the future.

This research is supported by products manufactured by Arthrex, Inc. Dr. Cole (an investigator on the study) receives extra money from Arthrex, Inc. for activities that are not a part of the

study. The activities are for consulting and license or royalty with Arthrex, Inc. It was determined by a conflict committee that the relationship was considered unlikely to affect your safety and/or the scientific quality of the study. This decision was given to the IRB for its review and approval of the study. If you would like more information, please contact Dr. Cole or Dr Yanke.

Who can you contact for more information about this study?
Questions are encouraged. If you have further questions about this study, you may email Carla Edwards, PhD at Carla_edwards@rush.edu or call the study doctor, Dr. Yanke at (312) 563-2880.

Who can you contact if you have concerns about your rights as a study participant?
Questions about the rights of research participants may be addressed to the Rush University Medical Center Office of Research Affairs at 1-800-876-0772.

What are your rights as a study participant?
Taking part in this study is voluntary. If you choose not to participate in this study or to leave the study at any time, your health care, benefits or relationship at Rush University Medical Center will not change or be affected. If you choose to leave this study and you do not want any of your information to be used, you must inform Dr. Yanke in writing at the address on the first page. Dr. Yanke may still use your information that was collected prior to your written notice.

SIGNATURE BY THE PARTICIPANT
By electronically signing, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study staff. You do not waive any of your legal rights by signing this consent form. You will be given a signed copy of this consent.