Official Title: PRP vs PRP Plus IGF for Patellar Tendinosis

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The Ohio State University Consent to Participate in Research and HIPAA Research Authorization

Study Title:	**Platelet-rich plasma versus Platelet-rich plasma plus concentrated Insulin-like growth factor for patellar tendinosis: a randomized comparative trial**
Principal Investigator:	**Michael Baria, MD, MBA**
Sponsor:	The Ohio State University

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

Key Information About This Study
The following is a short summary to help you decide whether or not to be a part of this study. More detailed information is listed later in this form. Platelet rich plasma injections are used to treat patellar tendinosis. Separately, another protein found in blood called insulin-like growth factor (IGF) has been shown to heal tendons, but it has never been used in combination with PRP. The goal of this study is to study if adding IGF to PRP is superior to PRP alone for treating patellar tendinosis.

1. Why is this study being done?

This study is being conducted to compare two treatments (platelet-rich plasma [PRP] and PRP combined with insulin-like growth factor [IGF]) for patellar tendinosis (or jumper's knee). PRP is made by taking your blood and concentrating it in a centrifuge to increase the amount of platelets. The platelets have important growth factors and proteins that are anti-inflammatory and may help tissues heal. Another important protein found in your blood is called IGF. This has been shown to help tendons heal. It is found in both PRP and plasma (the liquid component of blood). PRP has been used to treat jumper's knee and IGF has been shown to improve tendon healing, but it is unknown if adding IGF to standard PRP improves clinical outcomes. Our goal is to compare PRP with and without additional IGF for jumper's knee.

2. How many people will take part in this study?

38 patients with patellar tendinosis.

3. What will happen if I take part in this study?

You are being asked to participate in this research study because you have patellar tendinosis (jumper's knee). If you choose to participate, you will be randomized to receive 1 injection of PRP or PRP with added IGF. This means that a computer will randomly assign you to one treatment or the other. There is an equal chance of getting each treatment. Participants and doctors have no influence over which group you are assigned. PRP is a standard treatment for jumper's knee. The additional IGF is considered the experimental arm. Note, both groups will get PRP, while one group will get the additional IGF.

You will have 55cc (about 10 teaspoons) of blood drawn that will be concentrated for 15 minutes using a centrifuge. The same amount of blood will be processed to make both the PRP and concentrated IGF. Once processing is done, your skin will be injected with up to 5ml of 1% lidocaine (numbing medicine) to keep you comfortable. Then a total of 5ml of PRP (with or without IGF) will be injected into your tendon one time. A small amount (<1ml) of both your whole blood and PRP) will be analyzed in sports medicine to count the number of platelets in your blood and PRP.

Both procedures will take between 60-90 minutes.

You will be asked to fill out 5 short surveys about your knee pain. These will ask detailed questions about your knee pain with daily activity and sport, your activity level and your ability to perform certain sport related movements like jumping and cutting. You will complete these before the injection and then at 1,3 and 6 months. Your doctor will also perform ultrasound measurements of your tendon to determine tendon thickness and blood flow. These will be done at your injection visit and at 6 months. There is no additional charge for the ultrasound exam. These will be collected in a secured databased called

REDCap (which stands for research electronic data capture). These follow-up visits are part of routine care regardless of whether a patient is part of a research study.

4. How long will I be in the study?

6 months.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

The possible risks associated with participating in this research project are related to taking the blood and from the injection. These risks include the PRP blood draw risks include pain, bleeding, infection, fainting, bruising. From the knee injection, risks include pain at the injection site, redness, a brief increase in joint pain or swelling, and infection.
There is also the risk of breach of confidentiality. Specimens and data will be labeled as a numerical code. Your name will only be recorded on this document. No other link to you and your blood sample will exist.

7. What benefits can I expect from being in the study?

There will be no direct benefits to you.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled. PRP injections are available outside of the study. They are not covered by insurance and are an out of pocket expense. The IGF treatment is not available outside the study.

9. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office records. Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information.

Your name will not appear on any of those specimens and your participation will remain confidential. Specimens and data will be labeled with a numerical code.

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

You may also be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) research authorization form if the study involves the use of your protected health information.

10. Will my de-identified information (and bio-specimens) be used or shared for future research?

No.

11. What are the costs of taking part in this study?

Your insurance will be billed only for the cost of a standard ultrasound-guided injection. You are not being billed for the PRP or PRP+IGF. Ultrasound guided injections are covered by all insurance providers. The PRP / PRP + IGF is being paid for by the research study. Parking is free at the Sport Medicine Clinic. You will be financially responsible for all costs associated with treatment for all complications resulting from the procedure.

12. Will I be paid for taking part in this study?

You will receive a 10 dollar Amazon gift card at each of your 4 appointments (injection and 3 follow-up visits).

13. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

14. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

15. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

- Past and present medical records;
- Research records;
- Records about phone calls made as part of this research;
- Records about your study visits;

- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;

II. Who may use and give out information about you?

Researchers and study staff.

III. Who might get this information?

- The sponsor of this research. "Sponsor" means any persons or companies that are:
  - working for or with the sponsor; or
  - owned by the sponsor.
- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office record;

IV. Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
- Governmental agencies in other countries;
- Governmental agencies to whom certain diseases (reportable diseases) must be reported; and
- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

V. Why will this information be used and/or given to others?

- To do the research;
- To study the results; and
- To make sure that the research was done right.

VI. When will my permission end?

This study will end in 3 years so your permission will end March 1, 2023.

VII. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the researchers. If you withdraw your permission, you will not

be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study and receive research-related treatment. However, if you are being treated as a patient here, you will still be able to receive care.

IX. Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

16. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact ***Dr. Michael Baria at Michael.baria@osumc.edu or (614) 366-9324***.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact ***Dr. Michael Baria at Michael.baria@osumc.edu or (614) 366-9324.***

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form**.**

Printed name of subject	**Signature of subject**
	AM/PM
	Date and time
Printed name of person authorized to consent for subject (when applicable)	**Signature of person authorized to consent for subject (when applicable)**
Relationship to the subject	**AM/PM**
	Date and time

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	AM/PM
	Date and time
Printed name of witness	**Signature of witness**
	AM/PM
	Date and time