Official title: Microfragmented Adipose Tissue Versus Platelet-rich Plasma for Knee Osteoarthritis: a Randomized Comparative Trial

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

Study Title:	**Adipose-derived stem cells versus platelet-rich plasma for knee osteoarthritis: 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.

Two new treatments for knee arthritis are platelet-rich plasma (PRP) and adipose (fat) derived stem cells (ADSC). However, no study has ever compared them to see if one is better. This study will randomize participants to receive one of these treatments and follow clinical outcomes for 1 year to determine if one of these treatments is superior.

1. Why is this study being done?

This study is being conducted to compare two treatments (adipose-derived stem cells [ADSC] and platelet-rich plasma [PRP]) for knee arthritis. Both are derived from your own body and are currently used to treat knee arthritis, but they have never been compared. Our goal is to analyze how effective they are and how they compare to each other.

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

110 participants with knee arthritis

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

You are being asked to participate in this research study because you have knee arthritis. If you choose to participate, you will be randomized to receive 1 injection of either ADSC or PRP. 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 considered the standard treatment and the ADSC is considered the experimental arm.

For the ADSC injection, you will have a small amount (30ml; approximately 6 teaspoons) of fat taken from your abdomen, buttock or thigh. The area will be numbed using a local anesthetic. A needle will be used to remove the fat. The fat is then processed to remove oil and blood and liquefy the remaining contents from the fat. This will be done in the office and all in one visit. This will then be injected back into your knee. A small amount (<1ml) will be sent to an Ohio State laboratory to count the number of stem cells.

For the PRP injection, you will have 157mL (about 31 teaspoons) of blood drawn from your arm. This blood will be put into a centrifuge that will spin down the blood and pull out the PRP. The PRP will then be injected into your knee. A small amount (<1ml) of your whole blood and PRP will be analyzed in sports medicine to count the number of platelets in your blood and PRP. That same PRP sample will be analyzed for growth factors (proteins that can help tissue heal).

At the time of the injection, if your knee has excess fluid, this fluid will be removed prior to injecting the ADSC or PRP. We will analyze this fluid with a complete blood count and examination for inflammatory proteins.

Both procedures will take between 60-90 minutes.

You will be asked to fill out surveys about your knee pain before the injection and then at 1,3,6 and 12 months. Additionally, if you receive the ADSC injection, your doctor will see you 2 weeks after the injection to make sure the aspiration site looks healthy. All injections and follow up visits are covered by the research fund and your insurance will

not be billed. If you have had a knee MRI in the last year, your doctors will also look at it to judge the severity of arthritis.

4. How long will I be in the study?

1 year.

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 fat or blood, and from the knee injection. From taking the fat, risks include bruising, bleeding, pain, swelling, infection and creating a dimple in the skin where the fat was taken from. For 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 / fat 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. The PRP is available outside of this study; it is an out of pocket expense as it is not covered by insurance. The ADSC is not available outside this study.

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

There are no costs in taking part of this study. Parking is free at both the Jameson Crane Sports Medicine Institute and the Sports Medicine clinic located at Lewis Center. You will be financially responsible for all costs associated with treatment for all complications resulting from the procedure.

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

You will receive a 20 dollar Amazon gift card at the injection and the 1, 3, 6, and 12 month visit. By law, payments to participants are considered taxable income.

11. 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.

12. 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.

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

No.

14. 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.

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 may 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?

There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

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	Date and time AM/PM

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
	Date and time AM/PM

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

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

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