MedStar Health

Permission to Take Part in a Human Research Study

Title of research study: Peri-clitoral Injection of Platelet-Rich Plasma for Sexual Function

Investigator: Alexis Dieter, MD

Sponsor/Funding Source or Support: MedStar Health Research Institute / departmental and external funding (SHE+ Grant)

Financial Interest Disclosure: The investigators do not have a financial interest in platelet-rich plasma procedures or related commercial protocols. However, Dr. Cheryl Iglesia, a Sub-Investigator on this study, serves on the Advisory Board of SHE+ Foundation, the study's sponsor. This relationship has been disclosed to and is being managed by MedStar Health Research Institute's Conflict of Interest Committee.

Your study doctor may also be involved in your clinical care. You have the right to discuss this study with someone who is not part of the research team before deciding whether to participate.

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We invite you to take part in this research study because you are an adult natal female who is sexually active and may be eligible for a study evaluating platelet-rich plasma, also called PRP, for sexual function.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

The purpose of this study is to learn whether adding PRP injection around the clitoris improves sexual function when added to PRP injection into the front wall of the vagina. PRP is made from your own blood and contains a high concentration of platelets. Platelets release growth factors that may affect tissue healing, blood flow, and tissue remodeling. PRP is already being marketed for sexual function, but the added benefit and safety of the peri-clitoral injection have not been well studied.

How long will the research last and what will I need to do?

We expect that you will be in this research study for about 6 months.

You will be asked to complete screening, questionnaires about sexual function, one blood draw, one study procedure, and follow-up questionnaires at 6 weeks, 3 months, and 6 months. You will receive PRP in the front wall of the vagina. You will also be randomly assigned to receive either PRP or a sham injection (where the needle tip is inserted just under the skin but nothing is actually injected) around the clitoral area.

More detailed information about the study procedures can be found under "What happens if I say yes, I want to be part of this research?"

Is there any way being in this study could be bad for me?

The main risks are pain or discomfort from the blood draw and injections, bruising, bleeding, infection, vaginal discharge or odor, urinary symptoms, pelvic discomfort, temporary or persistent changes in sensation, numbness, hypersensitivity, or undesired changes in sexual arousal or genital sensation. Some questions about sexual function may feel private or uncomfortable. There is also a risk that your private information could be disclosed, although steps will be taken to protect your confidentiality.

More detailed information about the risks of this study can be found under "Is there any way being in this study could be bad for me? (Detailed Risks)"

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. Possible benefits to you may include improvement in sexual function, but this is not guaranteed. Possible benefits to others include improved understanding of whether peri-clitoral PRP is effective, tolerable, and safe when used for sexual function.

What happens if I do not want to be part of this research?

Participation in research is completely voluntary. You can decide to participate or not to participate.

Instead of being in this research study, your choices may include not participating, seeking routine clinical care, counseling or sex therapy, pelvic floor physical therapy, hormonal treatment if appropriate, medications, or other options recommended by your clinician. Anterior vaginal wall PRP injection is also available outside of this study, at an out-of-pocket cost, at clinics and medical spas that offer it for sexual dysfunction; this is not considered standard of care and would need to be discussed with your clinician.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Who can I talk to?

If you have questions, concerns, or complaints, talk to the research team at:

Margot G. DaBreo, MD, MPH

margot.dabreo@medstar.net

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may contact the MHRI IRB by phone at:

(301) 560-2912

Or by email at:

MHRI-ORIHelpDesk@medstar.net

You may choose to contact the IRB if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be studied?

We expect about 58 people at MedStar Health will be in this research study. This is a single-center study.

What happens if I say yes, I want to be in this research?

If you agree to participate, the study will include a baseline screening and treatment visit, a 6-week follow-up, a 3-month follow-up and a 6-month follow-up.

Screening and baseline visit:

- You will review and sign this consent form.
- The study team will confirm that you meet study criteria.
- You will answer questions about your medical history, medications, pregnancy status, and sexual function.
- You will complete the Female Sexual Function Index (FSFI).

Treatment procedure:

- You will have numbing cream applied to the vagina and near the clitoris about 20 minutes before the actual procedure.
- A trained staff member will draw about 40 to 60 mL of your blood, which is about 3 to 4 tablespoons.
- Your blood will be processed using the Arthrex PRP system to make about 2 to 4 mL of PRP.
- All participants will receive PRP injected into the front wall of the vagina.
- You will also receive two small superficial injections around the clitoral area, near the junction of the clitoris, clitoral hood, and frenulum. These injections will total about 1 mL.
- For the peri-clitoral injections, you will receive either PRP or a sham injection (this means that nothing will actually be injected but the needle may be inserted under the skin).
- About 10 to 15 minutes after the injection, you will complete a pain score using a visual analog scale.

Follow-up visits:

- At 6 weeks, you will complete the FSFI, Patient Global Impression of Improvement (PGI-I), and adverse event assessment.
- At 3 months, you will complete the FSFI, Patient Global Impression of Improvement (PGI-I), and adverse event assessment.
- At 6 months, you will complete the FSFI, Patient Global Impression of Improvement (PGI-I), and adverse event assessment.
- Follow-up may occur virtually or by another remote method when appropriate.

Study Activity	Screening	Baseline	6 Weeks	3 Months	6 Months
Informed consent	-	X	-	-	-
Eligibility screening	X	-	-	-	-
Scheduling of PRP procedure	X	-	-	-	-
Blood draw and PRP preparation	-	X	-	-	-
Anterior vaginal wall PRP injection	-	X	-	-	-
Peri-clitoral PRP or saline sham injection	-	X	-	-	-
VAS pain score	-	X*	-	-	-
FSFI questionnaire	-	X	X	X	X
PGI-I questionnaire	-	-	X	X	X
Adverse event assessment	-	-	X	X	X
Compensation	-	$50			$50

*The VAS pain score will be completed about 10 to 15 minutes after the procedure.

The treatment you get around the clitoral area will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment you get. You will have an equal chance of receiving peri-clitoral PRP or a sham injection. You will not be told which treatment you are getting; however, your study doctor will know.

This study does not include whole genome sequencing. You will not be contacted for future research unless you give separate permission or the IRB approves future contact.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for:

- Telling the study team about your medical history, medications, and any changes in your health.
- Completing questionnaires honestly and as completely as possible.
- Attending or completing the 6-week, 3-month, and 6-month follow-up assessments.
- Telling the study team promptly about any side effects, pregnancy, infection symptoms, pain, bleeding, sensory changes, or other concerns.
- Avoiding participation if you are pregnant or become pregnant during the study period. PRP has not been well studied in pregnancy and by signing this consent you acknowledge that there may be unforeseen risks if you are or become pregnant during the study period.

What happens if I say yes, but I change my mind later?

You can leave the research at any time and it will not be held against you.

If you decide to leave the research, please contact the investigator so the study team can discuss any safety concerns and ask whether you are willing to complete follow-up safety information. Data already collected before you leave the study may still be used for the research.

Is there any way being in this study could be bad for me?

The risks of this study include:

Blood draw risks:

- Pain, bruising, bleeding, lightheadedness, fainting, or rarely infection at the blood draw site.

Injection and procedure risks:

- Pain, pressure, burning, or discomfort during or after injection.
- Bruising, bleeding, swelling, irritation, vaginal spotting, discharge, odor, or infection.
- Urinary symptoms such as burning, urgency, frequency, or urinary tract infection symptoms.
- Pelvic pain, vulvar pain, clitoral pain, or pain with sexual activity.
- Temporary or persistent numbness, hypersensitivity, altered genital sensation, or undesired changes in arousal or orgasm. This may include increased sexual arousal.
- Vasovagal symptoms, such as dizziness, nausea, sweating, or fainting.
- Need for medical evaluation or treatment if symptoms occur.

Pregnancy risks:

The risks of PRP injection during pregnancy are not known. You should not be pregnant or become pregnant while participating in this study. If you become pregnant, tell the study team right away.

Questionnaire risks:

- Some questions about sexual activity or sexual function may feel private, embarrassing, or upsetting. You may skip any question you do not want to answer unless the information is needed to determine study eligibility or safety.

Privacy risks:

- There is a risk that your private information could be disclosed. The study team will take steps to reduce this risk, including storing study data in secure systems such as REDCap and limiting access to authorized study personnel.

Unknown risks:

In addition to these risks, this research may hurt you in ways that are unknown.

Costs:

There is no cost to you for the research PRP procedure or study-related assessments. You or your insurance may be billed for medical care that is not part of the research, including care needed for unrelated medical conditions or emergency care. If you have questions about cost, please talk with your study doctor or research staff.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB, representatives of MedStar Health Research Institute, and other representatives responsible for research oversight.

Study information may include your name, contact information, medical history, medications, sexual function questionnaires, procedure information, pain scores, adverse event information, and information from your medical record that is necessary for the study.

Study data will be collected and stored in secure research systems, such as REDCap. Paper records, if used, will be stored in locked or secure locations. Results may be published or presented at scientific meetings, but your name and other directly identifying information will not be included.

Any blood specimens collected as part of this research will be discarded immediately after PRP preparation and will not be stored or used for future research or testing. Other study information (such as your questionnaire responses and information from your medical record) will be used only as described in this consent form and will not be used to develop a new product or test.

HIPAA Authorization

We are committed to respecting your privacy and to keeping your personal information confidential. When choosing to take part in this study, you are giving us permission to use your personal health information, including health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number, or other identifying information.

The health information we may collect from you and use for this research includes:

- Information in your medical records necessary for this research.
- Results of physical examinations or procedure-related assessments.
- Medical history and medication information.
- Questionnaires related to sexual function and study outcomes.
- Records about the PRP preparation, injection procedure, and study device.
- Adverse event and safety information.

Once we have the health information listed above, we may share some of this information with authorized MedStar Health workforce members, the MedStar Health Research Institute Office for Research Integrity, the Institutional Review Board, laboratories or individuals involved in PRP

characterization, study monitors or auditors, and government agencies or public health authorities when required by law.

Any research information shared outside the study team will not contain your name, address, telephone number, or other personal identifier unless disclosure is necessary for review or is required by law or MedStar Health policy.

Those persons who get your health information may not be required by federal privacy laws to protect it. Some of those people may be able to share your information with others without your separate permission.

The results of this study may also be used for teaching, publications, or presentations at scientific meetings.

This research authorization will remain in effect until the end of the study unless you revoke consent for participation in this study. If you revoke consent, MedStar Health may not gather new information about you, or use or disclose your personal health information collected in this study for any purpose other than the research study described in this consent, unless MedStar Health obtains permission to do so from you or disclosure is required by law.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

PI's Name: Alexis Dieter, MD

Institution: MedStar Health Research Institute

Department: Urogynecology and Reconstructive Pelvic Surgery

Address: Physicians Office Building South Tower, 106 Irving St NW UNIT 405, Washington, DC 20010

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study if you do not allow this. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, payment or enrollment in any health plans, or eligibility for benefits.

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

Can I be removed from the research without my consent?

The person in charge of the research study can remove you from the research study without your approval. Possible reasons for removal include pregnancy, development of an exclusion criterion, a safety concern, inability to complete required study procedures, withdrawal of study approval, or a decision by the investigator that continuing in the study is not in your best interest.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research study.

What else do I need to know?

This research is being funded by MedStar Health Research Institute, departmental support, and other external funding via an organization focused on improving women's sexual health.

If you need medical care because of taking part in this research study, contact the investigator and medical care will be made available. Generally, this care will be billed to you, your insurance, or another third party. If you feel that you are having a medical emergency, you should go to the emergency room right away.

MedStar Health has no program to pay for medical care for a research-related injury.

If you agree to take part in this research study, your parking costs will be covered and we will pay you up to $100 for your time and effort: $50 after completion of the procedure visit and $50 after completion of the final 6-month follow-up.

Instead of being in this research study, your choices include not participating and seeking care outside the study. Non-study options may include counseling or sex therapy, pelvic floor physical therapy, hormonal therapy if appropriate, medications, anterior vaginal wall PRP injection available outside of this study at an out-of-pocket cost, or other treatments recommended by your clinician.

Most tests done on samples in research studies are only for research and have no clear meaning for health care. If PRP characterization is performed, the researchers will not contact you with individual results because these tests are for research purposes only.

Signature Block for Capable Adult

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Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	