MC2051 (16-001320)

A Study Evaluating Intraoperative Application of Platelet-Rich Plasma to the Neurovascular Bundles During Nerve-Sparing Radical Prostatectomy: Initial Technical Description and Prospective Early Postoperative Outcomes Analysis

NCT02957149

Document Date: 03/06/2019

MAYO CLINIC

Name and Clinic Number

Approval Date: **March 6, 2019**
Not to be used after: **September 6, 2019**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: A study evaluating intraoperative application of platelet-rich plasma to the neurovascular bundles during nerve-sparing radical prostatectomy: initial technical description and prospective early postoperative outcomes analysis

IRB#: 16-001320

Principal Investigator: Matthew T. Gettman, M.D. and Colleagues

Please read this information carefully. It tells you important things about this research study. A member of our research team will talk to you about taking part in this research study. If you have questions at any time, please ask us.

Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision.

To help you decide if you want to take part in this study, you should know:

- Taking part in this study is completely voluntary.
- You can choose not to participate.
- You are free to change your mind at any time if you choose to participate.
- Your decision won't cause any penalties or loss of benefits to which you're otherwise entitled.
- Your decision won't change the access to medical care you get at Mayo Clinic now or in the future if you choose not to participate or discontinue your participation.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you a copy of this form to keep. A copy of this form will be put in your medical record.

MAYO CLINIC

Name and Clinic Number

Approval Date: **March 6, 2019**
Not to be used after: **September 6, 2019**

CONTACT INFORMATION

You can contact …	At …	If you have questions about …
Principal Investigator: Dr. Matthew T. Gettman **Study Team Contact:** Vidhu Joshi	**Phone:** (507) 284-2297 **Phone:** (507) 538-6107 **Institution Name and Address:** Mayo Clinic 200 First Street, S.W. Rochester, MN 55905	▪ Study tests and procedures ▪ Research-related injuries or emergencies ▪ Any research-related concerns or complaints ▪ Withdrawing from the research study ▪ Materials you receive ▪ Research-related appointments
Mayo Clinic Institutional Review Board (IRB)	**Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681	▪ Rights of a research participant
Research Subject Advocate **(The RSA is independent of the Study Team)**	**Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchsubjectadvocate@mayo.edu	▪ Rights of a research participant ▪ Any research-related concerns or complaints ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information
Research Billing	**Rochester, MN:** (507) 266-5670	▪ Billing or insurance related to this research study

1. Why are you being asked to take part in this research study?

You are being asked to take part in this research study because you have decided to undergo radical prostatectomy with bilateral nerve-sparing as a treatment for your prostate cancer.

2. Why is this research study being done?

The purpose of this study is to see if substances from your own blood can help your nerves heal after surgery. With better healing this could improve your quality of life after surgery from a standpoint of urinary and sexual function.

3. Information you should know

Who is Funding the Study?

Since the study involves only the use of substances from your own blood and no use of study medications or devices, there is no company funding the study. Administrative costs for the study will be covered internally by Mayo Clinic.

Information Regarding Conflict of Interest:

Your healthcare provider may be referring you to this research study. If your healthcare provider is also an investigator on this study, there is the chance that his or her responsibilities for the study could influence his or her recommendation for your participation. If you prefer, your healthcare provider will be happy to refer you to another investigator on the research study team for you to decide if you want to participate in the study and to see you for the research study activities while you are in the study.

4. How long will you be in this research study?

You will be in this research study for about 18 months.

5. What will happen to you while you are in this research study?

Upon entry into the study you will be asked to complete quality of life assessments including the Sexual Health Inventory for Men and the Expanded Prostate Cancer Index Composite. These types of assessments are performed on all patients at Mayo Clinic that undergo radical prostatectomy. If baseline laboratories including a complete blood count with differential and serum prostatic specific antigen testing have not been performed, then these laboratory tests will be obtained. It is very common that these blood tests are performed as part of your workup to prepare you for radical prostatectomy.

At the time of your planned surgery, a sample of venous blood (approximately 6 ounces) will be obtained and processed to obtain a sample called platelet-rich plasma (sample size one-third of an ounce). Just before the conclusion of your radical prostatectomy, the surgical team will place the platelet-rich plasma on the neurovascular bundles.

Postoperatively, the study visits and monitoring follow the study visits and monitoring that are typically required after radical prostatectomy. Study inclusion does not subject you to additional tests or return visits.

On the first day after surgery, you will undergo a physical examination and review of your medical record and there will be a blood draw to assess complete blood count with differential that is typically performed after radical prostatectomy.

At approximately 1 week after surgery, you will undergo an additional postoperative check at which time the urinary catheter placed at the time of radical prostatectomy will be removed. At this time, you will also have a physical examination as well as an assessment for adverse events.

At approximately 3 months, 6 months, 9 months 12 months and 18 months after surgery, with an allowable visit window of +/- 14 days for each followup assessment, you will undergo a postoperative check where quality of life status will be assessed with the same questionnaires used before surgery. You will undergo a physical examination and have a serum prostatic specific antigen (PSA) sample drawn. This PSA sample drawn has an allowable testing window of +/- 21 days. You will be assessed for adverse study events. Study visits can be completed on-site, or if more convenient for you performed remotely with questionnaires mailed to the patient for completion and blood testing performed using a "mail-in" kit where blood is drawn locally and mailed to Mayo Clinic for analysis. It is anticipated that at these followup study intervals that contact with you can be face-to-face in clinic, by telephone, or by electronic mail.

6. What are the possible risks or discomforts from being in this research study?

The study involves a collection of blood (approximately 6 ounces). This collection of blood would be obtained after you are under a general anesthesia that is required for radical prostatectomy. The collection of blood would also be obtained from sites already being used for your radical prostatectomy. Potential risks of drawing blood include pain, bruising, lightheadedness, and/or fainting, or rarely, infection at the site of the needle stick. The collection of blood required in the study should not alone increase the risk of a blood transfusion. Blood in the study is obtained to isolate specific substances from your blood that promote healing of the neurovascular bundle. There is a low possibility that the substances from you blood could create adverse healing of the nerve bundle. There is also a possibility that if residual prostate tissue is present that growth of this tissue could occur. There is a low risk that if the residual prostate tissue was cancerous that the substances from your blood to contribute to a higher chance of cancer recurrence.

7. Are there reasons you might leave this research study early?

You may decide to stop at any time before your surgical procedure starts. You should tell the primary care team or the Principal Investigator if you decide to stop. You may also decide to leave the study at any time after you have had surgical removal of your prostate.

In addition, the primary care team and/or the Principal Investigator or Mayo Clinic may stop you from taking part in this study at any time if it is in your best interest for the following specific reasons: estimated blood loss from the prostate removal procedure of greater than 25 ounces or

visible and /or tissue laboratory evidence of prostate cancer that has moved outside the prostate into fat tissue around the prostate or into other anatomic sites in your body.

8. What if you are injured from your participation in this research study?

Where to get help:

If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries:

Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. You will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance.

9. What are the possible benefits from being in this research study?

This study may not make your health better. However, we believe that application of platelet-rich plasma to the nerve bundles at the time of surgery may reasonably improve your healing and allow you to experience better quality of life outcomes related to sexual function and urinary control.

10. What alternative do you have if you choose not to participate in this research study?

This study is only being done to gather information. You may choose not to take part in this study.

11. What tests or procedures will you need to pay for if you take part in this research study?

You won't need to pay for tests and procedures which are done just for this research study. These tests and procedures are:

- PRP (platelet rich plasma) application at the time of prostatectomy.

You and/or your insurance will need to pay for all tests and procedures that you have as part of your clinical care, including co-payments and deductibles.

Taking part in this research study may lead to added costs to you. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance company to see what services will be covered and what you will be responsible to pay. You will have to pay for any costs not covered by your insurance.

If you have billing or insurance questions call Research Billing at the telephone number provided in the Contact Information section of this form.

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

You won't be paid for taking part in this study.

13. What will happen to your samples?

Your blood samples will be used for this study. When the study is done, they will be destroyed.

14. How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study. All data collected from your participation will be stored in password-protected files on a computer.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission.

Health information may be collected about you from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

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

- To do the research.
- To report the results.
- To see if the research was done correctly.

If the results of this study are made public, information that identifies you will not be used.

Who may use or share your health information?

- Mayo Clinic research staff involved in this study.

With whom may your health information be shared?

- The Mayo Clinic Institutional Review Board that oversees the research.
- Other Mayo Clinic physicians involved in your clinical care.
- Researchers involved in this study at other institutions.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.

- The sponsor(s) of this study and the people or groups it hires to help perform this research.
- A group that oversees the data (study information) and safety of this research.

Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

Your Privacy Rights

You do not have to sign this form, but if you do not, you cannot take part in this research study.

If you cancel your permission to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

If you choose not to take part or if you withdraw from this study, it will not harm your relationship with your own doctors or with Mayo Clinic.

You can cancel your permission to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Subject Advocate at: researchsubjectadvocate@mayo.edu

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission lasts until the end of this study, unless you cancel it. Because research is an ongoing process, we cannot give you an exact date when the study will end.

MAYO CLINIC

Name and Clinic Number

Approval Date: **March 6, 2019**
Not to be used after: **September 6, 2019**

ENROLLMENT AND PERMISSION SIGNATURES

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

	/ /	: AM/PM
Printed Name	Date	Time

Signature

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

	/ /	: AM/PM
Printed Name	Date	Time

Signature