Low-Cost Platelet-Rich Plasma Injection for the Management of Hemarthropathy

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BACKGROUND

You are being invited to participate in a research study conducted by researchers at the University of Utah in collaboration with the Mountain States Hemophilia Network. This study is designed to investigate if a low-cost PRP method can aid in improving pain and function related to hemarthropathy in patients with bleeding disorders.

Hemarthropathy due to bleeding disorders, most commonly hemophilia, can result in significant complications related to chronic accumulation of blood products in the joint, leading to inflammation, pain, and joint degradation. Standard-of-care conservative treatments for this condition consist of physical therapy, oral pain medications, bracing, activity modifications, and corticosteroid injections. Most of these treatments are aimed at relieving pain but have little to no effect on the degenerative changes within the articular cartilage of patients with hemophilic synovitis/arthropathy. Further, pain medications and corticosteroid injections have significant known risks; thus, there is a significant need to identify nonsurgical treatment options for patients with hemophilic arthropathy.

A significant barrier to treatment for many patients with bleeding disorders is cost. Hemophilia has been documented as a disorder associated with a high economic burden on individuals and healthcare systems. Treatment of co-occurring conditions, such as synovitis and arthropathy, add significant cost to the already expensive treatment of hemophilia. This is particularly relevant in the case of PRP treatment, as this procedure is often very expensive for patients.

Low-cost platelet rich plasma (PRP) injection, however, is a method that can significantly reduce that cost while still offering effectiveness that is equivalent to standard-of-care. Thus, this method could allow for improved outcomes with less risk in hemarthropathy without raising the cost of treatment for patients. Importantly, this may also create a potential treatment option for patients with acute bleeds, that could be injected at the time of aspiration.

The study team has already validated a low-cost PRP method with a prior open-label trial in a single-center study for knee arthritis. The proposed project will be a prospective study demonstrating that low-cost PRP (around $10) can be performed safely in patients with hemophilia or other bleeding disorders, without the need for expensive equipment, while monitoring the outcomes of patients receiving the treatment.

NUMBER OF PARTICIPANTS

For this study, we have an enrollment goal of 20 joints (estimated 10-15 patients).

STUDY PROCEDURES

Your involvement in the study will include one office visit for injection, with the potential for another injection visit dependent on clinic/patient schedule and up to three (3) follow-up events (e.g. surveys) conducted via email, text message, in person and/or by telephone over a period of 6 months as follows:

- 1st Injection procedure treatment visit along with preliminary surveys (in-person)
- 2nd Injection procedure treatment visit three weeks after the initial injection (in-person)
- One-month follow-up survey (electronic)
- Three-month follow-up survey (electronic)
- Six-month follow-up survey (electronic)

INJECTION VISIT:

During the initial injection visit you will (if not already completed):

- Be approached by a member of the research team to discuss the consideration of taking part in the study if they meet the inclusion criteria of this study project;
- Review the informed consent document with a member of the study team;
- Be asked questions about your health, lifestyle and any current illnesses or medication(s) you are taking;
- Be asked to give a summary of all previous treatments that may have been performed to treat your hemarthropathy;
- Complete questionnaires on your pain, function and quality of life levels;
- Have your blood drawn by appropriate personnel (approximately 45mL);
- Have your blood processed using LC-PRP preparation method and its complete blood count analyzed using a cell counter;
- Have your appropriate joint numbed using local anesthetic (lidocaine 1%);
- Have your appropriate joint injected with the prepared LC-PRP by a board-certified physician using ultrasound guidance.

Your procedure outcomes will be assessed using patient questionnaires specific to your physical function. These are all different types of surveys and physical exams used to assess how well the injections work.

FOLLOW-UP:

You will have one in-person follow-up visit and three follow-up emails and/or phone calls/texts as part of research. You can come to the clinic for an evaluation at any time if you are experiencing any pain or side effects as part of standard of care.

1 Month: Patient questionnaires sent by mail, email, phone or text. You may receive a phone call to clarify any of your responses.
3 Months: Patient questionnaires sent by mail, email, phone or text. You may receive a phone call to clarify any of your responses.
6 Months: Patient questionnaires sent by mail, email, phone or text. You may receive a phone call to clarify any of your responses.
You may receive additional communications from the study team to assess any adverse events that occur in between the scheduled 1-month follow-up visit and subsequent follow-ups.

RISKS

As with any injection procedure, there are risks involved. These will be similar to standard-of-care injections. First, there is a risk of bruising, bleeding, or other minor, temporarily painful aspects. Second, although millions of PRP injections have been performed nationwide, zero case reports have been published on post-injection infections. However, there always remains a risk of an infection, which is quite serious. Only local inflammation has been reported in a case report to date, which resolved with time. It is possible to have a temporary worsening of your pain for up to a couple of weeks.
Because we need to collect information from your medical record for this study, there is a risk of loss of confidentiality. We follow strict privacy policies to minimize this risk.

UNFORESEEABLE RISKS

In addition to the risks listed above, you may experience a previously unknown risk or side effect.

BENEFITS

We cannot promise any benefits to you from your being in the study. PRP has been demonstrated to reduce pain for many musculoskeletal conditions. Subjects may have improved function and reduced pain after their injection. Some studies suggest that cartilage degradation may be slowed as well. The results of this study will be helpful in determining whether the treatment can be used successfully for treating this condition in future patients. In addition, it may be helpful in identifying patients who might best benefit from the treatment.

ALTERNATIVE PROCEDURES

You may choose not to participate in this study. If you do not want to take part in the study, there are other choices such as steroid injections, or other treatments as deemed appropriate by your physician.

PERSONS TO CONTACT

If you have questions, complaints, or concerns about this study, you can contact at Dr. Daniel Cushman at 801-587-5458. If you think you may have been injured from being in this study, please call Dr. Cushman at 801-587-5458. Dr. Cushman can be reached at this number during the hours of 8:30am and 5:00pm Monday – Friday. An Orthopedic resident is on-call 24 hours a day and can be reached by calling the University Hospital operator at 801-581-2121.

Institutional Review Board: Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints, or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

Research Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.

RESEARCH-RELATED INJURY

If you are injured from being in this study, medical care is available to you at the University of Utah as it is to all sick or injured people. The University of Utah has not set aside any money to pay the costs for such care. The University will work with you to address costs from injuries. Costs would be charged to you or your insurance company (if you have insurance), to the study sponsor or other third party (if applicable), to the extent those parties are responsible for paying for medical care you receive. Since this is a research study, some health insurance plans may not pay for the costs. By signing this consent form, you are not giving up your right to pursue legal action against any parties involved with this research.

The University of Utah is a part of the government. If you are injured in this study, and want to sue the University or the doctors, nurses, students, or other people who work for the University, special laws may apply. The Governmental Immunity Act of Utah is a law that controls when a person needs to bring a claim against the government and limits the amount of money a person may recover. See sections 63G -7-101 to -904 of the Utah Code.

VOLUNTARY PARTICIPATION

It is up to you to decide whether or not to take part in this study. If you decide to take part you are still free to withdraw at any time and without giving a reason. Refusal to participate or the decision to withdraw from this study will involve no penalty or loss of benefits to which you are otherwise entitled. If you don't take part, you can still receive all standard care that is available to you. This will not affect the relationship you have with your doctor or other staff, nor decrease the standard of care that you receive as a patient.

If you want to stop being in this study, please let the research doctor know. That way you can find out what should be done about your routine care outside of the study.

RIGHT OF INVESTIGATOR TO WITHDRAW

The investigator can withdraw you without your approval. Possible reasons for withdrawal include:

- It is not in your best medical interest to continue
- You do not follow instructions/non-compliance
- The study is terminated

COSTS AND COMPENSATION TO PARTICIPANTS

The costs of the injection procedure and visit will be covered by the study. All other visits and procedures you have are part of your normal care and will be billed to you or your insurance company.

By receiving SMS messages for surveys, you may incur standard SMS messaging costs from your mobile phone provider. You will not be compensated for your text messaging charges. Therefore, these costs will be your responsibility. We encourage you to understand the costs associated with sending and receiving text messages from your mobile phone provider before enrolling in this study.

Participants will be compensated with a $50 gift card per injection, potentially totaling $100 if both injections are completed.

NEW INFORMATION

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your research doctor will tell you about it and discuss with you whether you want to continue in the study.

AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION

Signing this document means you allow us, the researchers in this study, and others working with us to use information about your health for this research study. You can choose whether or not you will participate in this research study. However, in order to participate you have to sign this consent and authorization form.

This is the information we will use:

- Name
- Address
- Email address
- Telephone number
- Family medical history
- Allergies
- X-ray imaging and reports
- Current and past medications or therapies
- Operative reports, laboratory results, discharge and progress notes
- Any other personal health information that will be obtained from other sources to be used in the research record, including prior medical history, tests or records from other medical facilities
- Information from a physical examination, such as blood pressure reading, heart rate, breathing rate, temperature, and physical exam scores.
- Answers to questionnaires about pain and function

We will do everything we can to keep your information private but we cannot guarantee this. Study information will be kept in a secured manner and electronic records will be password protected. Study information may be stored with other information in your medical record. Other doctors, nurses, and third parties (like insurance companies) may be able to see this information as part of the regular treatment, payment, and health care operations of the hospital. We may also need to disclose information if required by law.

The University's Institutional Review Board and authorized members of the University of Utah who need the information to perform their duties (for example: to provide treatment, to ensure integrity of the research, and for accounting or billing matters).

Researchers at the Mountain States Hemophilia Network may also have access to your data so that more comprehensive and insightful analysis of the data can occur. If we share your information, we will not share your name or identifying information. We will label your information with a code number, so they will not know your identity.

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 this website at any time.

You may revoke this authorization at any time. This can be done verbally or in writing**.** You must either give your revocation in person to the Principal Investigator's or the Principal Investigator's staff, or mail it to University of Utah 590 Wakara Way, Salt Lake City, UT 84108 ATTN: Dr. Cushman. If you revoke this authorization, we will not be able to collect new information about you, and you will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.

You have a right to information used to make decisions about your health care. However, your information from this study will not be available during the study; it will be available after the study is finished.

If you do not want us to use information about your health, you should not be part of this research. If you choose not to participate, you can still receive health care services at The University of Utah Health.

This research is sponsored by the Mountain States Hemophilia Network (MSHN).

This authorization does not have an expiration date.

CONSENT

I confirm that I have read this consent and authorization document and have had the opportunity to ask questions. I will be given a signed copy of the consent and authorization form to keep. **I agree to take part in this research study and authorize you to use and disclose health information about me for this study, as you have explained in this document.**

_____

Participant's Name

_____

Participant's Signature Date

STATEMENT OF STAFF OBTAINING AUTHORIZATION AND CONSENT

- ❑ I have carefully explained to the participant the nature and purpose of the above study in language understood by the participant.
- ❑ I provided the participant enough time and an adequate place to read and review this form and discuss the study with study investigators and/or family members. I have answered the participant's questions to their satisfaction.
- ❑ The participant voluntarily agreed to participate in the study and personally signed and dated the consent prior to any study procedures being done.

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Name of Person Obtaining Authorization and Consent

_____

Signature of Person Obtaining Authorization and Consent Date

INTERPRETER STATEMENT: (For Non-English Speaking Participants Only) I confirm that I was present as an interpreter for the duration of the consent process for this research study. I confirm that I am qualified and have the necessary skills to provide interpretation between the participant's language and English. By signing this form, I confirm that I provided a full and complete interpretation of the exchange between the researcher obtaining consent and the participant, to the best of my ability.

_____
Name of Interpreter

_____ _____
Signature of Interpreter Date