

STANDARD PROCEDURE FOR REGISTERED NURSES(RN), PHYSICIAN ASSISTANT(PA), NURSE PRACTITIONER(NP) TO PERFORM PLASMA ENRICHED PLATELETS (PRP) INJECTIONS

A. Circumstances under which the RN,PA,NP may perform Plasma Enriched Platelet (PRP) injections.

1. Setting: Brentwood or
Alameda Medical Offices of Dr. Rex Moulton-Barrett
2. Supervision:
 - a. The Physician, NP and or PA who is trained and qualified will assess the patient prior to treatment to ensure the patient is a candidate for PRP. This will include a good faith examination. The patient's Medical History Questionnaire will be discussed in-depth with patient.(Questionnaire attached).
 - b. The RN/PA/NP may then treat the patient with PRP providing that the patient meets patient criteria, and Medical History Questionnaire has been completed.
 - c. The physician / NP /PA will review the treatment rendered and sign the chart upon review
3. Patient Conditions:
 - a. Consultation regarding patient's chief complaint completed
 - b. Ensure patient is a candidate for PRP by discussing the Medical History Questionnaire with the patient (please see attached questionnaire).
 - c. Patient is aware of potential adverse events following injection, these are headache, bruising and bleeding, infection, hematoma formation and possible temporary eyelid closure secondary to swelling
 - d. Patient must be at least 18 years of age, or parent/legal guardian may authorize treatment by filing out medical questionnaire and signing consent form.
 - e. Patient is ≤65 years of age.
 - f. Informed consent given and consent form completed.
4. Contraindications/Limitations:
 - a. Pregnancy.
 - b. Lactation
 - c. infection at the proposed injection site(s).
 - d. anticoagulation with INR > 1.8
 - e. nonsteroidal use within 10 days prior to glabellar injection
 - f. patients with lidocaine, marcaine, epinephrine, calcium citrate, betadine or chlorhexidine skin allergic reactions
 - g. autoimmune or neurological diseases associated with delayed wound healing
5. Precautions:

- a. General: Epinephrine should be available or other precautionary methods taken as necessary should an anaphylactic reaction occur.

II. PROTOCOL

A. Definition: The administration of the PRP is indicated for the temporary and possible semi-permanent improvement in the appearance of hair loss associated with male pattern baldness (MPB), Alopecia Areata (AA) and ageing face & neck (AFN) and neck in adult patients ≤ 65 years of age.

B. Assessment:

1. Subjective: The above patient conditions have been met.
2. Objective: The patient present with clinical evidence of MPB, AA and / or AFN.

C. Plan:

1. Storage: do not store any blood products
2. Equipments required for treatment:
 - Non sterile centrifuge arms, sterile inner plastic sleeves, +/- bag of ice
 - 21g butterfly needles
 - 8.5ml ACD vacutainer yellow tubes
 - Vacutainer needle holder sleeve
 - Alcohol wipe
 - Betadine Q tip
 - Topical anesthetic
 - Sterile white tube for second spin
 - 19 g needles, 5ml syringe
 - 19 g needle, 1 ml luer
 - Latex free blue disposable tourniquet
 - Cotton, tape
 - Mesoram 3 needle kit
3. Treatment for hair loss MPB and AA:
 - a. Wet hair with water at sink
 - b. Apply betadine iodine solution with gauze and gloves
 - c. topical anesthetic to area with tongue blade to scalp for injection for 20 minutes
 - d. Tourniquet upper arm, draw blood 21g butterfly needle vacutainer container base attachment
 - e. 4 x 8 ml ACD vacutainer yellow sterile tubes on covered needle at base of Vacutainer sleeve
 - f. Invert tubes 10 x's to mix with anticoagulant
 - g. First spin is $RCF = 900g = \underline{2000 \text{ rpms for 5 minutes}}$
($RCF = \text{Relative Centrifugal Force} = 1.12 \times \text{radius (mm)} = 200 \text{ our outside radius}) \times \text{rpm's}$)
 - h. Use 19 g spinal needle on 5 ml sterile syringe to remove the top layer of plasma (PPP) 55% by volume = 4mls, including the cloudy 'buffy' layer

with platelets (PRP) 1% by volume, discard yellow tube with remaining red cells at bottom

- i. Place top layer of 4 mls into a sterile clear vacutainer tube without anticoagulant
- j. Second spin is $RCF = 1000g = \underline{2100 \text{ rpms for 10 minutes}}$
- k. Remove and discard upper 3/4's = 3.2 mls using 19 g spinal needle on 5ml syringe
- l. Mix remaining 1/4 = 0.8mls with bottom platelet pellet + serum using a Freer spatula
- m. Use 19g spinal needle to draw up remaining 0.8ml on Luhr lock 1ml syringe x 4 total syringes
- n. Remove 19 g spinal needle and replace with a 3 mesoneedle 4mm to Luhr lock syringe
- o. Remove topical anesthetic and clean surface with betadine stick
- p. Inject PRP 0.2ml / 4mm depth (3 needles), 1cm intervals between injection needle sticks, 4 injections in total / syringe, with 4 syringes or a total of 16 injections, collagen activates PRP

4. Treatment fo Aging Face

- a. Apply betadine iodine solution with gauze and gloves
- b. topical anesthetic to area with tongue blade to face and neck for injection for 20 minutes
- c. tourniquet upper arm, draw blood 21g butterfly needle vacutainer container base attachment
- d. 4 x 8 ml ACD vacutainer yellow sterile tubes on covered needle at base of Vacutainer sleeve
- e. Invert tubes 10 x's to mix with anticoagulant
- f. First spin is $RCF = 900g = \underline{2000 \text{ rpms for 5 minutes}}$
($RCF=Relative \text{ Centrifugal Force}=1.12 \times radius \text{ (mm = 200 our outside radius) } \times rpm's$)
- g. Use 19 g spinal needle on 5 ml sterile syringe to remove the top layer of plasma (PPP) 55% by volume = 4mls, including the cloudy 'buffy' layer with platelets (PRP) 1% by volume, discard yellow tube with remaining red cells at bottom
- h. Place top layer of 4 mls into a sterile clear vacutainer tube without anticoagulant
- i. Second spin is $RCF = 1000g = \underline{2100 \text{ rpms for 10 minutes}}$
- j. Remove and discard upper 3/4's = 3.2 mls using 19 g spinal needle on

- 5ml syringe
- k. Mix remaining $\frac{1}{4}$ = 0.8mls with bottom platelet pellet + serum using 19 g spinal needle
- l. Use 19g spinal needle to draw up remaining 0.8ml on Luhr lock 1ml syringe x 4 total syringes
- m. Remove 19 g spinal needle and replace with meso 4mm x 3 needles to Luhr lock syringe
- n. Remove topical anesthetic and clean surface with betadine stick
- o. Inject PRP 0.2ml / 4mm depth (5 needles), 1cm intervals between injection needle sticks, 4 injections in total / syringe, with 4 syringes or a total of 16 injections, collagen activates PRP

5. Patient Education:

- a. Instruct patient no exercise for at least 8 hours after treatment.
- b. Patient not to recline for 4 hours.
- c. Instruct patient not to massage treatment sites for 4 days.
- d. Advise patient not to have microdermabrasion treatment for 7 days after injection.
- e. Inform patient bruising may occur and last 7-10 days.
- f. Inform patient redness and slight swelling may occur at the injection site.
- g. Inform patient that a 1-2 week eyelid droop (blepharoptosis) may occur secondary to swelling / hematoma.
- h. Patient to notify should any concerns or questions arise.

6. Follow-up:

- a. Patient to return in 7-12 days for suture removal
- b. Subsequent treatment scheduled 3-6 months later.
- c. The patient is to be educated that typically 2 treatments spaced at 3-6 month intervals will lead to some permanency of the result

7. Documentation:

The following information must be recorded in the patient's chart with each treatment:

- a. NP/MD prescription based on evaluation including good faith examination Amount of dilution and units injected per site.
- b. volume and composition of local anesthesia used to anesthetise the ports for injection and aspiration
- c. volume and composition of of tumescent liquid used.
- d. Specific areas treated: site, volume / injection & no. injections/treatment.
- e. Patient immediate response to treatment.
- f. Physician review and sign-off on patient charts within 7 working days after procedure.

III. REQUIREMENTS FOR RN

- A. Education:** Graduate of RN program with current California RN license.

B. Training:

1. Training by MD specific to product knowledge and proper technique. This training includes but is not limited to:
 - a. Mechanism of action of Botulinum Toxin A
 - b. Basic Theory of Treatment for Cosmetic Purposes
 - c. Facial and Scalp Anatomy and Muscle Function relating to the use of PRP
 - d. Pharmacokinetics
 - e. Preparation, and Injection Technique for PRP
 - f. Safety and efficacy issues
 - g. Contraindications and Precautions
 - h. Complications and side effect
 - i. Managing complications and adverse events (side effects)
 - j. Consultation, Assessment, and Patient education
 - k. Safe application of injection techniques and return demonstration
2. Formal education from PRP product representatives to increase knowledge, experience and proficiency in the proper administration of the product.
3. Experience:
 - a. No previous injectible experience necessary prior to training
 - b. Initial Evaluation: Successful completion of PRP training and demonstration of competency to MD.
4. Physician will review and sign-off all patient charts within 7 working days post procedure.
5. On-going evaluation:
 - a. MD will observe random and or quarterly injection technique including but not limited to PRP which are currently being used in the Alameda and or Brentwood offices of R. Moulton-Barrett,MD.
 - b. Injection technique includes evaluation of patient safety including sterile technique, needle management, patient tolerance / comfort, location and amount of injection relative to the degree of the rhytid and post injection management of the patient.
 - c. All evaluation will be documented in the RN evaluation book which is kept in the adminstraive office at all times.

IV. DEVELOPMENT OF PLAN

The Medical Director and Administrator have developed this Standardized Procedure and Protocol Policy (standing order) for the administration of PRP as a comprehensive working model, to ensure a safe and effective treatment of clients undergoing Botulinum Toxin A administration.

This model will be reviewed annually and documented in the minutes of the meeting and will be kept in the Administrative office of Rex Moulton-Barrett,MD

This Standardized Procedure and Protocol (standing orders) have been approved by:

Rex Moulton-Barrett,MD
Medical Director

Date: 3-6-2020

Good Faith / Appropriate Examination of New Patient to Practice of Dr. Rex Moulton-Barrett

Patient's Name: _____ Date: _____

Presenting History

- Botox/Xeomin
- Juvederm filler
- Voluma filler
- Belatero filler
- Sculptra
- Belafil/Artifil
- Skin care
- Laser hair
- Laser Vessels
- Laser skin tightening. Resurfacing
- Skin peel
- Skin Care with retinae
- ThermiSmooth and or ThermiVA
- Kybella to submental area
- PRP scalp
- PRP face and / or neck
- Novathreads
- Profound
- Other _____

Verification of No Contraindications of Proposed Treatment

- Patient not taking anticoagulant, no spontaneous bleeding disorder, no uncontrolled hypertension, not pregnant, no known allergies to above produce and not taking NSA's when contraindicated (botulinum toxin and glabella area, kybella, Voluma), no active infection of the head and neck

Appropriate Examination Findings

- PR _____
BP _____ / _____
- Chest clear and HS 1 and 2 heard with no murmur
 - No evidence of head and neck infection
 - No evidence of spontaneous bruising
 - Physical appearance & findings are consistent with patient's request for above requested therapy
 - Patient appears psychologically well adjusted & able to tolerate above requested procedure
 - Patient has been informed of the standardized procedures including the delegation of the treatment to the RN by the NP (employee Nurse Practitioner), PA (employee Physician's Assistant) and by the MD (Dr. Rex Moulton-Barrett) himself and the patient requests to proceed.

An appropriate examination was performed and the patient is cleared for the above named prescribed procedure / treatment.

Signed _____

MD, PA, NP

Dr. Moulton-Barrett's 2019 Pre-Treatment Instructions For Platelet Rich Plasma (PRP)

A few simple guidelines before your treatment can make a difference

If you develop a **fever, cold / flu, or develop a cold sore, blemish, or rash, etc. in the area to be treated** prior to your appointment, you must reschedule (*we will not treat you*).

It is recommended:

If you have a **special event or vacation coming** up that you schedule your treatment **at least 2 weeks** in advance (we prefer 3-4).

If you are being treated **in the lip area** and have a **history of Herpes (cold sores)** with outbreaks more than 4 times a year some practitioners recommended that you are pretreated with medication. This office recommends Valtrex 2GM the day before or the morning of the treatment and then another 2GM's.12 hours after the first dose. ****Please let us know that you need a prescription if you do not have this medication on hand. ****

Discontinue use of anti-inflammatory drugs (steroidal and non-steroidal) such as: Aspirin, Motrin (or any other Ibuprofen drugs) at least 3 days to 1 week before your treatment. With PRP, we "want" inflammation this is one of the mechanisms of how PRP does its work.

If you are or have been on **Systemic use of Corticosteroids (steroids) within 2 weeks** of treatment, we cannot treat you. **Consult your physician for approval to discontinue use of steroids and receive treatment.**

Discontinue use of any other blood thinning agents such as: Vitamin E, Essential Fatty Acids (EFA's and DHA's) etc. at least 10 days before and after treatment to minimize bruising and bleeding.

It is **recommended that you avoid:** Alcohol, caffeine, Niacin supplement, spicy foods, and cigarettes 3 days before and after your treatment. (*All of these may increase risk of bruising*)

Patient Signature & Date

Witness Signature & Date

Patient Name (print)

Witness Name (print)

Dr. Moulton-Barrett's 2019 Platelet Rich Plasma (PRP) Informed Consent Form

Platelet Rich Plasma, also known as "**PRP**" is an injection treatment whereby a fraction of blood (28-36cc's) is drawn up from your vein into 4-5 sterile vacuum tubes containing a small amount of calcium citrate to prevent the blood from coagulating. The blood is spun in a centrifuge to separate Red Blood Cells, Platelet Rich Plasma, Platelet Poor Plasma and Buffy Coat. The Platelet Rich Plasma and Buffy Coat removed and placed into another sterile tube. Platelets are very small cells in your blood that are involved in the clotting and healing process. When **PRP** is injected into the scalp or skin it causes a mild inflammation that triggers the healing cascade including an increased blood supply to that area. As the platelets organize they release a number of enzymes to promote healing and tissue responses including attracting stem cells and growth factors to the area which was injected. When treating injured or sun and time damaged tissue, PRP can induce a remodeling of the tissue to a healthier and younger state. The full procedure takes approximately 45 minutes. Generally 3-6 monthly treatments are advised. Touch up treatments may be done once a year after the initial group of treatments to boost and maintain the results.

PRP'S SAFETY has been established for over 20 years for its wound healing properties and *it's* proven effectiveness has extended across multiple medical specialties including hair growth, cardiovascular surgery, orthopedics, sports medicine, podiatry, ENT, neurosurgery, dental and maxillofacial surgery (*dental implants and sinus elevations*), urology, dermatology (*chronic wound healing*), and ophthalmology, cosmetic surgery. PRP's emergence into aesthetics and skin rejuvenation began in 2004 in Europe, Asia, Australia, and South America in countries such as The United Kingdom, Japan, Spain, Portugal, Switzerland and Argentina to name a few. Areas typically treated for aesthetic purposes and skin rejuvenation include: Crinkling skin around the eyes, cheeks and mid face, neck, jaw-line, chest and décolletage, back of hands and arms, lips, and to stimulate hair growth on scalp. Almost all skin tones show that **PRP** is safe and effective because your own enriched plasma is used.

BENEFITS of PRP: Along with the benefit of using your own tissue therefore virtually eliminating allergies, there is the added intrigue of mobilizing your own stem cells for your benefit. **PRP** has been shown to have overall rejuvenating effects on the skin including: improving skin texture, thickness, fine lines and wrinkles, increasing volume via the increased production of collagen and Elastin, and by diminishing and improving the appearance of scars. The most dramatic results to date have been the crepey skin problems in areas such as under the eyes, neck, and décolletage. It is not designed to replace cosmetic surgery as there are some cases where *t h o s e* procedures would be more appropriate. Other benefits include: minimal down time, safe with minimal risk, short recovery time, natural looking results; no general anesthesia is required.

CONTRAINDICATIONS: PRP used for aesthetic procedures is safe for most individuals between the ages of 18-80. Parental consent is required for patients under 18. There are very few contraindications, however, patients with the following conditions are not candidates: 1) Acute and Chronic Infections 2) Skin diseases (i.e. SLE, porphyria, allergies) 3) Cancer 4) Chemotherapy treatments 5) Severe metabolic and systemic disorders 6) Abnormal platelet function (*blood disorders, i.e. Haemodynamic Instability, Hypofibrinogenemia, Critical Thrombocytopenia*) 7) Chronic Liver Pathology 8) Anti-coagulation therapy, 9) Underlying Sepsis and 10) Systemic use of corticosteroids within two weeks of the procedure.

RISKS & COMPLICATIONS: Some of the Potential Side Effects of Platelet Rich Plasma include: 1) Pain at the injection site; 2) Bleeding, Bruising and/or Infection as with any type of injection; 3) Short lasting pinkness/redness (flushing) of the skin; 4) Allergic reaction to the solution; 5) Injury to a nerve and/or muscle as with any type of injection; 6) Itching at the injection site(s); 7) Nausea /vomiting; (The following are possible with any simple injection and not specific to PRP Therapy).8) Dizziness or fainting; 9) Temporary blood sugar increase; 10) Swelling; 11) Minimal effect from the treatment.

ALTERNATIVES to PRP: Alternatives to PRP are: 1) Do Nothing; 2) Surgical intervention may be a possibility; 3) Injections with neurotoxins; 4) Injections of dermal filling agents; 5) Laser & light based treatments like Pulsed Light; 6) chemical peels, 7) In the case of hair: topical and oral minoxidil, oral propecia and other topical hair enhancing products including Folara.

RESULTS: Results are generally visible at 4 weeks and continue to improve gradually over ensuing months (3-6) with improvement in texture and tone. Advanced wrinkling cannot be reversed and only a minimal improvement is predictable in persons with drug, alcohol, and tobacco usage. Severe scarring may not respond. Current data shows results may last 18-24 months. Of course all individuals are different so there will be variations from one person to the next.

PHOTOGRAPHS: I authorize the taking of clinical photographs and their use for scientific and educational publications and presentations. I understand my identity will be protected.

CONSENT: My consent and authorization for this elective procedure is strictly voluntary. By signing this informed consent form, I hereby grant authority to Dr. Moulton-Barrett/ and his employee Nurses, Physician Assistants, Nurse Practitioner(s) to perform Platelet Rich Plasma (PRP) injections to area (s) discussed during our consultation, for the purpose of aesthetic enhancement, hair growth and/or skin rejuvenation. I have read this informed consent and certify I understand its contents in full. All of my questions have been answered to my satisfaction and I consent to the terms of this agreement. I agree to adhere to all safety precautions and instructions after the treatment. I have been instructed in and understand post treatment instructions and have been given a written copy of them. I understand that medicine is not an exact science and acknowledge that no guarantee has been given or implied by anyone as to the results that may be obtained by this treatment. I also understand this procedure is "elective" and not covered by insurance and that payment is my responsibility. Any expenses which may be incurred for medical care I elect to receive outside of this office, such as, but not limited to dissatisfaction of my treatment outcome will be my sole financial responsibility. Payment in full for all treatments is required at the time of service and is non-refundable. I hereby give my voluntary consent to this PRP procedure and release the clinic, its medical staff, and specific technicians from liability associated with the procedure. I certify that I am a competent adult of at least 18 years of age and am not under the influence of alcohol or drugs. This consent form shall be binding upon my spouse, relatives, legal representatives, heirs, administrators, successors and assigns. I agree that if I should have any questions or concerns regarding my treatment / results I will notify this office at 510 864-1800 or 925 240-8775 and/or the provider immediately so that timely follow-up and intervention can be provided.

Patient Signature Date

Witness Signature Date

Physician Signature Date

Patient Name (print)
(print)

Witness Name (print)

Physician Signature

Dr. Rex Moulton-Barrett's PRP Work Sheet 2019

Name of Patient: _____

Date of service: _____

Location of treatment Alameda Brentwood

Procedure: Hair Skin: _____

Site of Venipuncture: _____

Number(s) of 8-9ml purple top tubes collected: 1 2 3 4 5

Numbers of tubes white top buffy layer plasma collected: 1 2 3 4 5

Duration of time mixing platelet pellet with remaining plasma:

Volume of platelet pellet and plasma remaining after discarding top 3/4 of white tube: 0. ____ mls

Injection with : Mesotherapy triple 31 g single gauge: _____ microcannula gauge: _____

Number of Injections sites for remaining PRP: _____

Volume of PRP used per site: 0. ____ mls

Location of Injections

Comments: _____

