The Effect of Platelet Rich Plasma on Non-scarring Alopecia
PI: Hooman Khorasani, MD
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The Effect of Platelet Rich Plasma on Non-scarring Alopecia:
A Randomized, Controlled Clinical Trial

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Investigators:
Hooman Khorasani, MD
Richard Torbeck, MD
Aaron S. Farberg, MD
Hayley Leight, MD

Study Site:
Mount Sinai School of Medicine
Department of Dermatology
[redacted]
New York, NY 10028

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Introduction and rationale:

The purpose of this study is to evaluate the clinical efficacy of platelet rich plasma (PRP) injections for non-scarring alopecia in women. A randomized, placebo-controlled clinical trial will be performed where patients with non-scarring alopecia will either receive injections of their own PRP or injections of normal saline (placebo). Patients in the treatment group (Group A) will have a small amount of their own blood drawn (22 mL) and have their PRP injected into their scalp. The injections will be given at weeks zero, four, eight, and twenty-four. The number of injections in the PRP group will vary slightly based on how much PRP is able to be extracted from the patients' blood. However, typical number of injections will range from 10-30 with 0.2 mL injected into each site. The placebo group (Group B) will be given the same schedule but will receive sham injections only composed of normal saline (3 mL, total of 15 injections with 0.2 mL in each injection site). In place of the blood draw, the placebo group will have a sterile needle placed into the ante-cubital fossa but no blood will be taken from the patient. Both groups will have clinical data collected at all visits, including a screening visit before enrollment and a final assessment visit at week 40, for a total of six study visits per patient. Data collection will include representative photographs of the scalp and measurements of hair thickness using a specialized camera called a folliscope as well as a standard digital camera for macroscopic photos. No hair samples will be needed for photographs and there will be no biopsies taken during this study. The results from the two groups will then be compared. Patients will also be given small surveys at the beginning, middle and end of the study to assess for any pain, adverse effects, and the level of improvement the subjects have seen.

In summary, all study participants will have a screening visit before enrollment, 4 study visits for subdermal scalp injections, and one final assessment visit at week 40. Data analysis and comparison will be measured with macroscopic photography and microscopic hair follicle photography as well as with patient surveys.

Objective:

To evaluate the clinical efficacy of platelet rich plasma (PRP) injections for non-scarring alopecia in women .

Description of Study:

Subjects receiving PRP injection will undergo the following protocol:
All subjects will be asked to wear dark, non-visible goggles during the blood draw in the beginning of the visit. 22 mL of whole blood will be drawn from a peripheral vein and then processed through a centrifuge two times thus obtaining about 3-6 mL of plasma rich in leukocytes and platelets. The doctor will leave the room for approximately 10 -15 minutes to prepare the PRP injections. The subject's scalp will be cleansed topically with alcohol and then injected with the patient's PRP using a 25-gauge needle in a 3 mL Luer-lock syringe into the subcutaneous scalp. Injections will be 1-2 cm part and the amount injected will be 0.2 mL per injection. The number of injections in the treatment group will vary from patient to patient depending on the amount of PRP that was able to be harvested from the blood draw. However,

patients can expect anywhere from 10-30 injections. There will not be more than 30 injections in any patient during any study visit.

Subjects receiving placebo (preservative-free normal saline) will undergo the following protocol: All subjects will be asked to wear dark, non-visible goggles during the blood draw period in the beginning of the visit. The patient in the control group will have a sterile needle placed by a certified doctor or medical assistant into the ante-cubital fossa of the arm but no physical blood will be taken out of the patient. The doctor will leave the room for approximately 10 -15 minutes to prepare the normal saline injections. The subject's scalp will be cleansed topically with alcohol and then injected with 0.9% normal saline, for a total of 3 mL, (0.2 mL in each injection site and 15 total injections). The injection sites will be 1-2 cm apart.

Protocol Schedule:

1. Study visit 1: screening visit with the clinical research team after referral from Hair loss clinic with prior baseline blood work already reviewed
2. Study visit 2: Injection #1, week 0: FULL PHOTO EVALUATION AND SURVEY #1
3. Study visit 3: Injection #2, week 4
4. Study visit 4: Injection #3, week 8: FULL PHOTO EVALUATION
5. Study visit 5: Injection #4, week 24: FULL PHOTO EVALUATION AND SURVEY #2
6. Study visit 6: final assessment visit only, no injections, week 40 : FULL PHOTO EVALUATION AND SURVEY #3

At each injection visit (weeks 0,4,8,24) the participant will first speak to the doctor and discuss any adverse reactions. Photographs will be taken as mentioned above. On certain visits, as listed, patient surveys will be given to subjects to assess PRP, any improvements in the alopecia, pain or other adverse effects. The data from these surveys will be used in the final stages of the research to look at patient aggregated data. After this, the injection protocol will be followed as detailed above and the patient will be scheduled for their next appointment.

Patients will be contacted within 12-24 months post study to be informed of results of the study. If possible and if published by this time, a copy of the paper outlining the trial will also be provided to patients.

Primary endpoint:

Photographs of the scalp (with standard digital camera) and trichoscopy photographs (with specialized camera called folliscope to visualize hair follicles and measure hair thickness, density, and caliber where the follicle exits the scalp) will be used for primary evaluation endpoint.

Secondary endpoint:

Additionally, surveys as detailed above will provide qualitative participant information regarding improvement with procedure, pain or other adverse effects.

Subject Selection:

Inclusion Criteria

1. Must understand and voluntarily sign an informed consent form
2. Must be female between the ages of 18 and 65 years at the time of consent
3. Must be able to adhere to the study visit schedule and other protocol requirements
4. Documented baseline blood work either in chart review or documented by the hair loss clinician- blood work needed includes normal TSH and ferritin as per the laboratory standards, platelet count above 150,000 platelets per microliter and a negative pregnancy test for any pre-menopausal women—all blood work must be documented as normal within 12 months prior to the start of the study

Exclusion Criteria

Because of the parameters of the study, a chart review and subject interview will be conducted during the screening visit. "Yes" answers to any of the following will result in inability to participate in the study.

- *Previous or current use in the last 1 year of finasteride, minoxidil topical or oral, or spironolactone*
- *A diagnosis of non-androgenic alopecia (i.e.: another diagnosis for the alopecia)*
- *Abnormal Baseline ferritin, TSH, platelet count, and a negative urine pregnancy test in any pre-menopausal female in past 12 months.*
- *Active skin disease (Psoriasis or severe seborrheic dermatitis) of the scalp*
- *Active scalp infection*
- *Severe active blood infection*
- *Cuts or abrasions on the scalp*
- *History of surgical hair restoration*
- *Current or recent malignancy*
- *History of systemic chemotherapy or radiation*
- *History of thyroid dysfunction*
- *History of autoimmune disorder (specifically Graves disease, hashimoto thyroiditis, or systemic lupus erythematosus)*
- *Tendency to develop keloids*
- *Continued medically necessary daily use of Nonsteroidal anti-inflammatory or Vitamin E*
- *Platelet dysfunction syndrome*
- *Thrombocytopenia less than 150,000*
- *Diagnosis of hypofibrinogenemia*
- *Anticipated pregnancy or trying to become pregnant in the next 2 years*
- *Current or active Tobacco use*

Informed Consent:

Prior to entering the study, the investigator or designated assistant will explain to each subject the nature of the study, its purpose, procedures, expected duration, alternative therapy available, and the benefits and risks involved in study participation. Subjects will be given the consent document, the opportunity to ask questions, and will be informed of their right to withdraw from the study at any time without prejudice. After this explanation and before any study-specific procedures have been performed, the subject will voluntarily sign and date and informed consent form, including photographic consent form. Prior to participation in the study, the subject will receive a copy of the signed and dated written informed consent form.

Platelet Rich Plasma (PRP) And Saline Injection Guidelines:

3-6ml of PRP will be injected into randomly assigned subjects. The same procedure will be carried out for administration of the normal saline. Both procedures are detailed above.

Safety Evaluations:

Adverse Reactions

At each visit, the subjects will be assessed for any of the following possible AEs:

-injection site pain

-ecchymoses

-systemic effects, including nausea, fatigue, malaise, flu-like symptoms, headache, runny nose, diplopia, dysarthria, generalized muscle weakness, asthenia, blurry vision, ptosis, dysphagia, dystonia, urinary incontinence, breathing difficulties, rash.

Prior And Concomitant Medications:

At the initial visit, prior and concomitant medications and therapies will be reviewed as may pertain to exclusion from the study.

Restricted Medications/Treatments:

The restricted medications and treatments prior to the study initiation are those that the investigator feels may indicate that the patient has an unstable medical condition, as described in the exclusionary criteria.

Subject Withdrawal Or Discontinuation:

Subjects may choose to withdraw from the study or may be withdrawn by the investigator at any time without prejudice to their future medical care. Any subject who does not comply with the inclusion/exclusion criteria may be withdrawn from further participation in the study.

Discontinuation Procedures:

Any subject who wishes to discontinue prematurely from the study should return to the study center for an End of Study Visit.

Adverse Event Definitions:

An adverse event (AE) is any untoward medical occurrence in a patient or clinical investigation subject which is temporally related to protocol procedures, including administration of a

pharmaceutical product at any dose, but which does not necessarily have a causal relationship with the treatment. The term AE also applies to laboratory findings or results of other diagnostic procedures that are considered to be clinically relevant (e.g., that required unscheduled diagnostic procedures or treatment measures or result in withdrawal from the study). Surgical procedures themselves are not adverse events; they are therapeutic measures for conditions that require surgery. The condition for which the surgery is required is an adverse event, if it occurs or is detected during the study period. Planned surgical measures permitted by the clinical study protocol and the condition(s) leading to these measures are not adverse events, if the condition(s) was (were) known before the start of study treatment.

Adverse events will be recorded according to CTCAE guidelines.

A serious adverse event (SAE) is any AE or adverse drug reaction that at any dose results in any of the following outcomes:

- death
- life-threatening adverse event
- inpatient hospitalization or prolongation of existing hospitalization
- persistent or significant disability/incapacity
- congenital anomaly/birth defect

An event may be considered serious when, based upon appropriate medical judgment; it jeopardizes the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed above.

A life-threatening adverse event is any AE or adverse drug reaction that at any dose places the patient or subject, in the view of the investigator, at immediate risk of death from the reaction as it occurred. It does not include a reaction or event that, had it occurred in a more severe form, might have caused death.

Materials And Supplies:

Study Device

Eclipse will manufacture and provide the PRP collection kits for use in the study. The PRP will then be injected into the scalps of patients for the treatment arm of the study. Normal saline will be used for the placebo arm of the study.
Syringes and 25 G needles will be used.
Gauze, alcohol swabs will be used to prepare the injection sites.

Institutional Review Board:

Prior to beginning this study, approval must be obtained from the Institutional Review Board at the Mount Sinai Medical Center.

Data Analysis:

Individual efficacy variables, the sum of those variables, and safety parameters will be analyzed.