Platelet-rich Plasma (PRP) for Endometrial Regeneration and Repair NCT02825849

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Summary of PRP Study Protocol

Study Period 1: Randomized controlled trial:

- 8 subjects randomized to PRP
- 5 subjects randomized to control.
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Patients will be randomized to standard treatment procedures versus standard treatment plus intrauterine infusion of platelet rich plasma (PRP). Both groups of patients will receive the same initial workup, consultation and evaluation, treatment, surgical interventions or cycle monitoring, ultrasounds and embryo transfer. The only difference between the two groups will be the intrauterine infusion of PRP based on randomization and that the experimental group will have an extra blood draw for PRP preparation.

The only difference in clinical practice that the experimental group in this randomized controlled trial would have that differed from the "control" population, would be the 1-2 intrauterine infusion of PRP based on randomization and that the experimental group will have an extra blood draw for PRP preparation. The standard of care procedures for patients with Asherman's Syndrome is as following.

All patients will undergo the hysteroscopic procedure in the operating room under general anesthesia for resection of intrauterine adhesions. The degree of the adhesions will be rated by the physician performing the surgery using ASRM classification guidelines. The scar and adhesions will be resected with hysteroscopic scissors and grasper, until the endometrium appears to be reached with visualization of vascularity. Thereafter, a pediatric 8-10-gauge Foley catheter will be placed into the uterine cavity, and the balloon will be inflated with 3 ml of normal saline. The catheter extending out of the uterus will be tied off with 2 ties of 2'0' silk and then the catheter will be cut distally to the knots, with no parts extending outside of the vagina. Patients will be discharged home the same day and instructed to start on 30 days of 2 mg estradiol twice daily per usual protocol, with 10 days of medroxyprogesterone acetate 10mg daily for the last 10 days of estradiol. All patients will receive doxycycline antibiotic 100mg twice a day for the duration of the intrauterine Foley catheter placement (5-7 days). They will have endometrial lining assessment with transvaginal ultrasound 2 and 4 weeks during the first month post-procedure. Second look hysteroscopy will be performed after 1 month to assess the uterine cavity. Patients will be asked to record the menstrual flow diary before treatment and for the next 1-3 months (Menstrual Assessment Chart, from Higham et al, BJOG 1990). Future fertility treatment will be planned on individual bases per patients' preferences. For the patients with thin endometrial lining, the standard of care guidelines for hormone replacement in the setting of frozen IVF cycles will be used as a reference (not a part of experimental protocol) chosen by the primary physician. The primary doctor will manage the entire hormone replacement based on the clinical knowledge, expertise and standard of care practices. Endometrial lining measured by ultrasound is recorded at every visit. Patients will be undergoing standard controlled frozen embryo transfer (FET) cycle and will be started on oral contraceptive pills (OCP, Desogen) to block the endogenous hormone production for 14-28 days, per usual protocol. GnRH agonist (Leuprolide acetate, Lupron) will be started for pituitary suppression 6-7 days before the last OCP dose, subcutaneously at a dose of 10 units (0.5mg) daily, which will continue until start of progesterone. Patients will present for baseline ultrasound per standard

practice on second day of menses after OCP withdrawal. If baseline ultrasound normal, patients will start Vivelle estradiol patch 0.1mg every 36 hours with increasing dose, again per standard protocol. Surveillance ultrasound lining check will be scheduled on cycle day 12. Per our standard protocol, minimal endometrial strip thickness of 7mm is required before initiation of progesterone. If patients meet the criteria for embryo transfer, it will be performed according to the standard of care. If the lining is thin, patient will be randomized to control or study group.
7.11 INSTRUMENTS: List all questionn

Study period 2 (10/2/2018):
Prospective recruitment of patients opting for PRP (no randomization; all received intervention.).

- 14 Subjects received PRP using the above protocol