

Autologous Platelet Rich Plasma (PRP) Intradermal Injections for the Treatment of Vulvar Lichen Sclerosus

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Objectives: Exploratory study designed to evaluate the efficacy and safety of autologous Platelet Rich Plasma (PRP) injections for the treatment of vulvar lichen sclerosus.

Methods: Nine patients with biopsy proven active vulvar lichen sclerosus were recruited. This study consists of a 2 week screening period and a 12-week treatment period. Patients receive two separate treatments of PRP separated by 6 weeks. Each treatment consists 5 ml of autologous PRP (Magellan® Autologous Platelet Separator System, Arteriocyte Medical Systems, Hopkinton, MA) injected sub-dermally and intra-dermally. A repeat biopsy was performed 6 weeks after the second PRP injection. The primary efficacy variable as measured by two blinded pathologists is the change in inflammation between pre and post treatment biopsies. Secondary endpoints included changes from baseline in pruritus and vulvar burning using VAS scales and change of Investigator's Global Assessment (IGA) of the severity of the disease (0 to 3 scale).

Results: Seven out of the 9 participants completed the protocol and 2 participants were lost to follow up prior to having post-treatment biopsies. Of the 7 patients who completed the protocol, two blinded pathologists determined that 4 women had decreased inflammation on their post treatment biopsies, one woman had no change in inflammation, and 2 women had "minimal" increase in inflammation on their post treatment biopsies. A T-test compared the IGA scores for the patients pre and post treatment and showed a significant difference between the pre (mean 2.4) and post (mean=1.6) $p = 0.016$.

Conclusions: The effectiveness of PRP is based on its high level of growth factors such as PDF, TGF- β , and EGF. These growth factors are important in modulating mesenchymal cell proliferation, and extracellular matrix synthesis during healing. The vast majority of published literature shows that autologous PRP has minimal risk of scar tissue formation or serious adverse events. The results of this exploratory study suggest that PRP injections decreased histopathologic inflammation in women with vulvar LS without the potential side effects associated with topical or systemic immunomodulators.