Effectiveness of Ultrasound Guided Platelet Rich Plasma Injections in the Sacroiliac Joint

NCT03122119

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**Protocol Synopsis for Research Project Involving Human Subjects**

**PROTOCOL INFORMTION**

*Title of Research Activity*: Effectiveness of Ultrasound Guided Platelet Rich Plasma Injections in the Sacroiliac Joint

**A. Specific Aims**

The objective of this research is to identify the effectiveness of Platelet-Rich Plasma (PRP) injections into the sacroiliac (SI) joint in relieving low back pain.

**B. Experimental Design and Methods**

The research design for this study will be a prospective clinical trial evaluating the improvement in low back pain secondary to SI joint dysfunction pre and post PRP injection. No control group will be utilized in our study due to the ethics of research in withholding treatment to patients. Patients who are found to be candidates will be offered the PRP injection without cost until the number of available donated kits is exceeded. Each subject will serve as their own control by reporting pre-injection pain levels as well as pain levels immediately post-injection, 2 weeks, 4 weeks, 3 months, and 6 months post-injection.

Our hypothesis is, "Platelet-Rich Plasma Injections in the Sacroiliac Joint using ultrasonography in conjunction with physical examination and Point of Maximal Tenderness will produce statistically significant pain relief for more than 3 months as measured by the Numeric Rating Scale for Pain (NRS)."

Experimental design will be a nonrandomized trial (or quasi-experiment). The specific study design to be used is pretest-posttest design. The independent variable will be the PRP injection. The dependent variables of interest include the NRS and Oswestry Disability Index (ODI) recording pre-injection, immediately post-injection, 2 weeks, 4 weeks, 3 months, and 6 months, post-injection.

1) Methods and Procedures

Data in this study will be collected quantitatively by assessing the patient's pain prior to the injection as well as at 2 weeks, 4 weeks, 3 months, and 6 month follow up using the NRS and ODI.

2) Data Analysis and Data Monitoring

The following data will be recorded from each patient: current pain scale using the NRS and their functionality using the ODI.

**Study Protocol**

**Summary**

We would like to analyze and obtain confidence intervals and mean reduction of NRS and ODI for the following:

Confidence Interval for the following (for both NRS and ODI):

1. Baseline – 2wks
2. Baseline – 4wks
3. Baseline – 3 months
4. Baseline – 6 months

**Statistical Analysis Plan**

The Oswestry Disability Index (ODI) uses a questionnaire to assess pain levels and the impact pain has on a patient's daily life. This was chosen as the primary outcome measure and was calculated based on a questionnaire then converted to a percentage for objective comparison.

The secondary outcome measure was the Numeric Rating Scale for Pain (NRS). This rating scale provided another objective tool based purely on pain severity for comparison of changes in pain levels pre- and post-injection.

Statistical analysis was performed using SPSS 25, XLStat 2019.1.2, and R3.5.2. Variables were assessed for normality of distribution by using the Shapiro-Wilk test and Jarque-Bera test. ODI and NRS scores were compared from baseline to 2 weeks, 4 weeks, 3 months, and 6 months using ANOVA and paired ttest. Discrete variables were summarized as means and standard deviations.