

STATISTICAL ANALYSIS PLAN

Official Title: Ultrasound-guided platelet-rich plasma versus whole blood injection for the treatment of gluteus medius tendinopathy: a double-blind randomized controlled study

NCT02978833

Date: August 6, 2018

Sample Size Analysis

Proposed analysis: Two-way repeated measures analysis of variance

Alpha level: 0.01

Beta or power level: 0.864

Number of groups being compared: 2

Effect size or change expected between groups: 15-point change between groups

Resulting number per group: 30

Total sample size required: 72

Data Analysis Plan

Descriptive analyses of the patient population will include reporting means (with standard deviations) for continuous variables and frequencies (with percentages) for categorical or discrete variables. Independent samples t-test (or non-parametric equivalent) will be used to assess the differences in continuous variables among the two study groups, while chi-square or Fisher's exact test will assess the association between categorical or discrete variables against the study groups. Odds ratio and their 95% confidence intervals will be calculated to measure the strength of that association.

We powered our study to demonstrate an MCID of 15 points in the non-arthritis hip pain score (NAHS) with estimated standard deviation of ± 20 points. Using that estimate, it was determined that sample sizes of 30 patients in each group achieves 86% power using a two-way repeated measures analysis of variance model with 4 follow-up points and statistical significance set to alpha equal to 0.01. To account for a potential loss-to-follow-up rate of 20%, we plan to increase enrollment for each treatment by 6 patients.