

The Effect of Micro Fragmented Adipose Tissue (MFAT) on Knee Osteoarthritis

Statistical Analysis Plan

NCT03467919

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Power:

Based on an a priori power analysis, a sample size of 40 patients would yield at least 80% power to detect the minimally clinically important difference in KOOS subscales between groups when using a two-sample t-test. This power analysis plans for a 3:1 ratio of ADSC and corticosteroid patients.

Analysis:

Descriptive statistics about the cohort are reported using means, ranges, and standard deviations (SDs) for continuous variables and using counts and percentages for categorical and ordinal variables.

Overall changes in PROs (VR-12, KOOS, Lysholm, Marx, Tegner, and Pain Frequency) for the entire cohort at 3, 6, 12, and 24 months were analyzed using paired t-tests and Wilcoxon signed-rank tests. Changes in PROs between the ADSC and corticosteroid groups were analyzed using two-sample t-tests and Mann-Whitney U-tests, while changes in PROs within each treatment group were analyzed using paired t-tests and Wilcoxon signed-rank tests. All analyses were completed in RStudio using a two-sided level of significance of 0.05.

The individual features of the MOAKS instrument were analyzed between treatment groups at both 6 weeks and 1 year using Fisher's exact tests. Changes in MOAKS features from 6 weeks to 1 year between treatment groups were analyzed two separate ways: ordinal, Likert scale variables were analyzed as numeric using Mann-Whitney U-tests, while binary categorical variables were analyzed using Fisher's exact tests. All analyses were completed in RStudio using a two-sided level of significance of 0.05.