Injection Therapy in Patients with Lateral Epicondylitis

ID: 2018/12

Document Date: 05/13/2018

Study Protocol

The study was a single-blind randomized clinical trial with parallel group and allocation ratio was 1:1. Ethical approval of the study was obtained from the Inonu University Clinical Research Ethics Committee (No.2018/12). Volunteers meeting eligibility criteria gave informed written consent prior to enrolment by the trial administrator. The patients who met the inclusion criteria randomly assigned into two groups (PrT group, HA group) in a ratio of 1:1 through the stratified block randomization method. The patients and the researcher who were responsible for the analyzing of the data were blinded to the randomization results. All data were collected at baseline, 6 and 12 weeks. Furthermore, patients were monitored if they had any side effects from the injection such as ecchymosis, redness, increasing pain or reduced range of motion.

Statistical Analysis Plan

The SPSS (version23; SPSSInc., Chicago, IL, USA) was used to conduct the analysis. Descriptive statistics were presented as mean ± standard deviation and percentage. In the evaluation of categorical variables, Pearson Chi-Square Test and Fisher's Final Test were used. Suitability of variables to normal distribution were analyzed using visual (histogram and probability graphics) and analytical methods (Shapiro-Wilk Test). Differences between the two groups at baseline and at six and twelve weeks were tested by Independent-samples t test. Paired t tests were used for within-group analyses. P values <0.05 were considered significant.