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TITLE

Effect of Subacromial Sodium Hyaluronate Injection on Rotator Cuff Disease: A double-blind, Placebo-controlled Clinical Trial

Alireza Moghtaderi

Medical University of Esfahan, Iran

Introduction: Rotator cuff disease is one of the most common causes of shoulder pain. Ice, rest, anti-inflammatory medications, exercise, and cortisone injection are common treatments. Even treatment may lead to surgery. In this study we evaluated the effect of sodium hyaluronate on rotator cuff disease and we hypothesized that sodium hyaluronate (Fermatron) would provide better results than the placebo.

Materials and Methods: This randomized, double-blind, placebo-controlled clinical trial was performed among 40 patients admitted with rotator cuff disease without complete tear in Alzahra hospital, Isfahan, Iran. Patients were categorized in two groups (Fermatron and Placebo). Twenty patients (Fermatron group) had ultrasound guided injections of 20mg/wk of sodium hyaluronate into the subacromial bursa for 3 consecutive weeks. With the same injection protocol twenty patients (Placebo group) were injected by 2 ml of normal saline solution.

Results: There were no significant difference between two groups according to demographic characteristics ($p=0.507$), baseline Constant score ($p=0.4$), or Visual Analog Scale (VAS) score ($p=0.617$). Fermatron group had better VAS scores than placebo group 1, 2 and 3 weeks after injections ($p<0.05$). Also, in this group mean Constant score had significant improvement 12 weeks after the last injection ($p=0.04$). However mean VAS decreased in both groups after treatment but independent t-test showed significantly better results in Fermatron than Placebo group ($p<0.001$). Constant score, also, improved in both groups with statistically more increment in Fermatron group ($p<0.001$). No significant adverse effect was noted.

Conclusion: Ultrasound guided subacromial injections of sodium hyaluronate are effective in treating rotator cuff disease without complete tears.

Key words: Sodium Hyaluronate, Rotator Cuff Disease, Demographic Characteristics, Baseline Constant Score, Visual Analog Scale.