University of Mosul

College of Medicine

Assessment of the Effect and Safety of Etanercept in Patients with Ankylosing Spondylitis in Ninevah Governorate

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Summary

Ankylosing spondylitis (AS) is an inflammatory disorder of unknown etiology that primarily affects the axial skeleton; peripheral joints and extra-articular structures are also frequently involved. Tumour necrosis factor (TNF) blockers have greatly improved the condition of patients with active AS. Etanercept is a recombinant DNA-derived protein composed of tumor necrosis factor receptor (TNFR) linked to the Fc portion of human IgG1. This study was designed to assess the effectiveness and safety of etanercept in patients with ankylosing spondylitis in Ninevah Governorate.

A single-center open-labeled prospective study was conducted on 43 patients with AS diagnosed according to the modified New York criteria of ankylosing spondylitis. Patients received etanercept 50mg subcutaneously once weekly and were evaluated for effectiveness at baseline, at weeks 4 and 12 through evaluation of disease activity and functional status by using Bath ankylosing spondylitis disease activity index (BASDAI) and Bath ankylosing spondylitis functional index (BASFI) respectively. BASDAI 50 was used to assess the response rate. In all the patients the following laboratory tests were done: hemoglobin (Hb), WBC count, neutrophil count, platelet count, erythrocyte sedimentation rate (ESR), C reactive protein(CRP), aspartate aminotransferase (AST) alanine aminotransferase (ALT), blood urea and serum creatinine. The safety of etanercept was assessed at each study visit in all patients who received at least one dose of study medication. Safety assessments included adverse events, premature discontinuations, and effects on some hematological and biochemical parameters.

The mean age of patients was (36.55±8.47) years, males represented (90.7%) of the cases, and the mean disease duration was

(9.6±5.90) years. A significant decrease in BASFI and BASDAI was found after 4 weeks and 12 weeks of treatment compared to baseline (p=0.000). BASDAI 50% response was achieved by (42.5%) of the patients after 4 weeks and by (65%) after 12 weeks of treatment with etanercept. There was a significant decrease in the mean ESR and CRP after 4 and 12 weeks of treatment with etanercept. There was a significant reduction in WBC (p=0.003) and neutrophil count (0.000) after 4 and 12 weeks of treatment. However, there were no significant changes in serum ALT, AST, urea, and creatinine ($p > 0.05$ for all). In total, 26 adverse events were reported, and most of them were of no clinical significance. Only three patients discontinued treatment as a result of adverse events; one patient developed uveitis and 2 patients developed a covid-19 infection. The most common adverse event is injection site reactions (20.9 %), Headache (4.7 %), sore throat (4.7 %), and itching (2.3%) were also found during etanercept treatment.

In conclusion, etanercept 50 mg subcutaneously once weekly for 12 weeks was an effective treatment in patients with AS. In addition, it was a well-tolerated and relatively safe drug.