Aim of this study is to evaluate the efficacy and safety of combined therapy of Etanercept (ETN) and methotrexate (MTX), and methotrexate alone, in patients with rheumatoid arthritis (RA).

Patients with RA were treated in combination with etanercept (with doses of 25 mg subcutaneously twice weekly), and oral MTX (doses of 15 mg weekly), and alone methotrexate in period of two years, in Rheumatology Department of Internal Clinic in Pristina. Clinical response was assessed using American College of Rheumatology (ACR) criteria and the Disease Activity Score (DAS28) in 25 patients with RA.

Of total numbers of 25 patients (3 of them were males and 22 were females) with mean age of 54,92 years, 10 or 40% of patients were treated with combined therapy (ETN plus MTX) and 15 or 60% of patients with monotherapy (MTX). The addition of etanercept in treatment resulted with improvement of acute phase reactants as erythrosedimentation rate 41,1 vs 10,3 first hour and C-reactive protein 40,8 vs 6. In the group treated with MTX alone the acute phase reactants has not significant changes. Before treatment the severity of the disease was high, where in group with combined therapy (ETN plus MTX) DAS28 was 5,32, and in the group with monotherapy of MTX DAS28 was 5,69. After 2 years of treatment we had significant changes in the results of DAS28, where in group treated with ETN plus MTX DAS28 was 2,12, and there were no radiographic changes while in the group of patients treated with MTX DAS28 was 3,14 and from 15 patients 3 of them had radiographic changes from stage II to III of RA. The group with combined therapy (ETN plus MTX) showed significantly less radiographic progression, less value of acute reactants.

According to our results we can conclude that etanercept in combination with methotrexate reduced disease activity, slowed radiographic progression and improved clinical manifestations more effectively than methotrexate alone within period of 2 years. During the treatment no serious adverse events were noticed with combination treatment of etanercept and methotrexate.

Key words: rheumatoid arthritis, treatment, methotrexate, etanercept