The use of tocilizumab in combination with methotrexate in Indonesian rheumatoid arthritis patients (PICTURE INA Study)

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Abstrak

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Background Aim of this research is to assess the efficacy and safety of tocilizumab in combination with methotrexate in Indonesian patients with moderate to severe active rheumatoid arthritis who have an inadequate response to non biologic DMARDs.Methods This was a interventional, prospective, single arm, multicenter, study in Indonesian male or female patients aged > 18 years old, with a diagnosis of RA for > 6 months based on ACR 1987 revised criteria with moderate to severe disease activity DAS28 score > 3.2 after > 12 weeks of non biologic DMARDs treatment. The treatment consisted of tocilizumab, 8 mg/kg, intravenous, every 4 weeks for a total of 6 infusion in combination with oral MTX 10 until 25 mg every week. Efficacy was assessed based on the percentage of patients achieving low disease activity state DAS28 < 3.2, percentage of patients achieving reduction > 1.2 point of DAS28, percentage of patients achieving remission DAS28 < 2.6, and percentage of patients with ACR20, ACR50, and ACR70 responses. Descriptive statistics will be used for presentation of results.Results 100 percent patients reached low disease activity DAS28 < 3.2 at last study visit week 24 and clinically significant improvement reduction at least 1.2 units at every visit in DAS28, both for ITT or PP patients. Remission DAS28 < 2.6 was observed in 82.1 percent ITT patients and 93.1 percent PP patients on last study visit. ACR20, ACR50, and ACR70 were achieved in 20 percent, 34 percent, and 34 percent ITT patients, and 7 percent, 24 percent, and 62 percent PP patients on week 24. There were 3 out of 39 patients 7.69 percent with adverse events and serious adverse events that resulted in discontinuation of TCZ treatment, consisting of 1 patient with SAE of sepsis ec acquired community pneumonia, 1 patient with SAE of pneumonia tuberculosis, and 1 patient with AE of candidiasis. Most common adverse events were hepatic dysfunction 30.7 percent, hypercholesterolemia 23.1 percent, followed by arthralgia 20.5 percent Twelve percent of patients needed dose modification due to elevated liver enzyme elevated ALT/SGPT level. Conclusion Tocilizumab seems to be efficacious and likely to have good safety profile in non biologic DMARD nonresponsive RA patients of PICTURE INA study.