Clinical comparison of renogen, a biosimilar epoetin-a, with the originator, eprex, in chronic kidney disease anemia in Indonesia: a preliminary study

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Abstrak

Background: treatment of erythropoietin (EPO) is essential in chronic kidney disease (CKD) patients to maintain optimal hemoglobin (Hb) level. Renogen is a biosimilar epoetin-α, and Eprex is the originator epoetin-α. This study aimed to compare the efficacy and tolerance of Renogen with Eprex in CKD anemia.

Methods: Renogen and Eprex were compared in a randomized (2:1), open-label study for 8 weeks, proceeded by 4 weeks adjustment (maintenance) phase, in anemic CKD patients undergoing HD in Cipto Mangunkusumo General Hospital, Jakarta, from June 2017 to October 2018.

Results: a total of 45 patients (31 received biosimilar EPO and 14 received originator EPO) were included in the study. At baseline, mean (SD) Hb levels were 10,9 (0,74) g/dL and 10,9 (0,61) g/dL in biosimilar and originator EPO groups, respectively. At end of study (8 weeks), mean (SD) Hb levels were 10,5 (1,28) g/dL and 11,0 (1,13) g/dL in biosimilar EPO and originator EPO groups, respectively. The proportion of patients with Hb levels maintained within the target range (>10 g/dL) during 8 weeks randomization phase were 58,1% and 71,4% in biosimilar EPO and originator EPO, respectively (p=0,60; NS). There were no significant difference in epoetin dose between the 2 groups, and there was no drug-related adverse event in either group.

Conclusion: Hb level at >10 g/dL could be maintained for 8 weeks of treatment with both originator and biosimilar EPO (more consistent with originator EPO and more fluctuations with biosimilar EPO), with similar epoetin dose and no drug-related adverse event.