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Comparison between erythropoietin alfa biosimilars and reference product in anemic patients of chronic kidney disease

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Patent expiration for erythropoietin alfa in Europe in 2004 led to development of biosimilar erythropoietin alfa, recombinant human erythropoietin (rhuEPO) is used for treatment of anemia due to renal failure. Our study aimed to evaluate clinical efficacy of two biosimilars from different manufacturers relative to innovator product Eprex (Cilag.AG. Switzerland). Clinical efficacy is assessed as a function of therapeutic equivalence of a biosimilar and innovator product through a parallel, randomized single blind study in 35 patients with anemia result from chronic kidney disease and had not received EPO previously. The primary efficacy endpoint was the serum EPO level which measured by enzyme immunoassay (ELISA) during 120 hours after administration of a single 4000 IU dose. The secondary endpoints were the hematological parameters (the hemoglobin, hematocrit, total serum iron levels and reticulocyte) before and after treatment. This study confirmed presence of significant difference between reference erythropoietin (EPO) alfa group (Eprex) and biosimilars erythropoietin alfa groups (A) in terms of serum EPO profile but biosimilars have similar EPO profile to Eprex and no significant difference with Eprex in clinical efficacy and hematological parameters.

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