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ORIGINAL ARTICLE

Investigation of the Efficacy of a Biogeneric Recombinant Human Erythropoietin Alfa in the Correction of Post-Transplantation Anemia: A Randomized Comparative Trial with Eprex

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SUMMARY

Background: **Recombinant human erythropoietin is the cornerstone of therapy for anemia associated with chronic kidney disease or renal transplantation. However, it is not affordable and available for all patients. The present randomized double-blind trial compared the efficacy and safety of a biogeneric erythropoietin, Epolyrec, with the original product, Eprex, in correcting post-transplantation anemia (PTA).**

Methods: **Fifty patients who had undergone kidney transplantation surgery and had a hemoglobin level of < 11 g/L and a hematocrit of < 30% were recruited. These patients were randomly assigned to Epolyrec (n = 25) or Eprex (n = 25) at a dosage of 80 - 120 IU/kg body weight, three times/week. Patients were followed-up for two months unless they achieved the target levels for hemoglobin (1 g/L increase compared to baseline) and hematocrit (2 - 3% increase compared to baseline). Hemoglobin, hematocrit, and complete blood count with differential (CBC/DIFF) were evaluated at baseline and at months 1 and 2 of study. Other biochemical parameters were assessed at baseline and at the end of trial.**

Results**: Serum hemoglobin and hematocrit progressively increased from baseline to month 2 in both Epolyrec ($p = 0.001$) and Eprex ($p < 0.001$) groups, with no significant difference between the groups ($p > 0.05$). Mean corpuscular hemoglobin (MCH) and platelet count showed a significant increase during the course of the trial in both Epolyrec ($p = 0.041$ and 0.004 for MCH and platelet count, respectively) and Eprex ($p = 0.036$ and 0.003) groups. However, no significant change was observed between the groups regarding erythrocyte count, mean corpuscular volume, white blood cell count or reticulocyte count from baseline to the end of trial in any of the groups ($p > 0.05$). The incidence of adverse events were generally low in both groups and without any significant difference between Epolyrec and Eprex ($p > 0.05$).**

Conclusions: **Epolyrec was equivalent to Eprex with respect to efficacy and safety. Hence, Epolyrec could represent a much more affordable and available biogeneric alternative to Eprex in correcting PTA.**

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KEY WORDS

Erythropoietin, transplantation, anemia, kidney, biogeneric, bioequivalency

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