

혈액투석 환자의 빈혈 치료에 있어서 고용량의 피하 Recombinant Human Erythropoietin 의 유효성 및 안전성 평가 : 다기관 무작위 배정, 공개, 제 3상 연구

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A Randomized, Open, Multicenter Trial to Evaluate the Efficacy and Safety of Subcutaneous Administration and Once Weekly or Fortnightly Subcutaneous Administration Compared with Intravenous Administration of Recombinant Human Erythropoietin in Hemodialysis

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Introduction : Anemia can be effectively treated with erythropoietin. This study aimed to evaluate the safety and effectiveness of high dose erythropoietin in hemodialysis patients.

Materials and methods : The patients (n=169) were classified into 3 groups; intravenously (IV) one to three times a week (control, n=56), subcutaneously (SC) one to three time a week (group 1, n=56), and SC once weekly or fortnightly (group 2, n=57). Each erythropoietin dose per session was given 2,000 to 4,000 unit in control and group 1. High dose of erythropoietin (8,000 to 12,000 unit) was given to group 2. These patients were followed up to 16 weeks.

Results : The per-protocol analysis included 134 patients. The differences in mean hemoglobin levels between baseline and final period were similar between control and group 1 (0.85 ± 0.18 vs 1.33 ± 0.20 g/dL, p-value=0.0796) and between control and group 2 (0.85 ± 0.18 vs 0.73 ± 0.20 g/dL, p-value=0.6462). Hemoglobin levels remained stable during the study with no differences among 3 groups. The total weekly dose of erythropoietin at final period was significantly lower in group 2 compared to control and group 1 ($7,229 \pm 2,162$ in group 2 vs $8,746 \pm 4,522$ in group 1, $8,804 \pm 4,843$ unit in the control group). Both treatment regimens were well tolerated with no severe side effects. High dose once weekly or fortnightly SC administration of recombinant human erythropoietin is as safe and effective as two or three times weekly IV or SC administration of the same total dose in maintaining hemoglobin levels in hemodialysis patients.

Conclusion : High dose once weekly or fortnightly SC administration of recombinant human erythropoietin is as safe and effective as two or three times weekly IV or SC administration of the same total dose in maintaining hemoglobin levels in hemodialysis patients.

Key Words : 고용량, 혈액투석, 에리쓰로포이에틴

Recombinant human erythropoietin, High dose, Hemodialysis