

한국인 투석 환자에서 Mircera를 이용한 빈혈 치료의 유효성과 안정성에 대한 제 3상 임상 연구

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Mircera Corrects Anemia in Korean Patients With Chronic Kidney Disease on Dialysis: Results from a Randomized Controlled Multicenter Study

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Introduction and Aims: This study investigated the efficacy of Mircera, a continuous erythropoietin receptor activator, for correcting anemia in patients with chronic kidney disease on dialysis. In addition, long-term safety and tolerability of Mircera was assessed for the subsequent 24 weeks of the extension period.

Methods: In this open-label, randomized, multi-center, parallel group, phase III study, eighty patients (18 yr) who were not receiving any erythropoietic stimulating agents for more than 8 weeks were randomly assigned (1:1) to either intravenous Mircera once every 2 weeks (n=39) or epoetin beta thrice-weekly (non-comparative control, n=41) during a 24-week correction period. The target hemoglobin during the correction phase was within the range of 11 to 13 g/dL and an increase in Hb from baseline 1 g/dL without RBC transfusion. Patients who achieved the target in both groups were assigned to Mircera once monthly for a 24-week extension period.

Results: The primary end point was Hb level response rate (increase in Hb level $>or=1$ g/dL and Hb level $>or=11$ g/dL without RBC transfusion) in the intent-to-treat population. Hb response rates were 79.5% and 87.8% for Mircera and epoetin beta, respectively, and it showed that Mircera once every 2 weeks was as effective as epoetin beta for correcting anemia. The time to response indicated that the correction of anemia was slower in Mircera group compared with epoetin beta group. Median time to response was approximately 12 weeks in Mircera and 10.3 weeks in epoetin beta. The time to response in both groups is relatively long with Korean patients. Mircera and epoetin beta were well tolerated.

Conclusion: This study demonstrates that once every 2 weeks intravenous administration of Mircera corrects anemia effectively and safely in patients with CKD on dialysis.

Key Words: 미세라, 빈혈, 투석

Mircera, Anemia, Dialysis