

Therapeutic efficacy of a biosimilar epoetin alfa in dialyzed patients previously treated with human recombinant erythropoietin: a phase-III, multicenter, clinical trial

Amel Harzallah¹, Karim Zouaghi², Afef Dridi³, Karima Boubaker¹, Soumaya Beji², Mohamed Ayari⁴, Fethi El Younsi¹, Fatma Ben Moussa², Adel Kheder¹

¹ Department of Internal Medicine A, Charles Nicolle Hospital, ² Department of Nephrology, Rabta Hospital, Tunis, ³ Dialysis Unity of Manouba, Manouba, ⁴ Dialysis Unity of Rades Foret, Ben Arous, Tunisia.

Corresponding author:

Amel Harzallah
Department of Internal Medicine A
Charles Nicolle Hospital, Tunis, Tunisia
E-mail: amel_harz@yahoo.fr
Tel: + 21698559342

Abstract:

Anemia is a frequent complication in patients with chronic renal failure (CRF). However, human recombinant erythropoietin (rHu-EPO) has revolutionized the management of anemia in chronically dialyzed patients. Epomax[®] is a new biosimilar rHu-EPO alfa manufactured in Tunisia (Medis Laboratories). The aim of this study was to evaluate the efficacy and tolerance of Epomax[®] in dialyzed patients with CRF in a phase-III, multicenter, clinical trial. Fifty-three dialyzed patients (mean age 47.7 ± 13 years) who received a stable dose of rHu-EPO (Hemax[®]; manufactured by Biosidus Laboratories) subcutaneously were switched to Epomax[®] via the same route of administration. At inclusion, mean systolic pressure was 132 ± 18 mmHg and mean diastolic pressure was 79 ± 8 mmHg. Mean hemoglobinemia was 10.2 g/dL and median ferritin level was 667 ng/mL. The main objective of the study was to assess the variations in hemoglobin levels between inclusion and the period of evaluation. After a follow-up of 43 days, mean hemoglobinemia was 10.5 g/dL. There was no significant difference between the two treatments. Few adverse events were reported during the study. In dialyzed patients, Epomax[®] treatment was effective at maintaining hemoglobin levels at target concentrations and was well tolerated.

RESUME :

L'anémie est une complication fréquente au cours de l'insuffisance rénale chronique. L'érythropoïétine humaine recombinante (rHu-EPO) a révolutionné la prise en charge de l'anémie chez les dialysés chroniques.

EPOMAX est une nouvelle érythropoïétine humaine recombinante biosimilaire de type alfa fabriquée en Tunisie. L'objectif de cette étude est d'évaluer chez l'insuffisant rénal chronique dialysé, l'efficacité et la tolérance d'EPOMAX à travers un essai clinique multicentrique de phase III.

Cinquante trois patients dialysés recevant de la rHu-EPO à dose stable par voie sous-cutanée ont reçu de l'EPOMAX par la même voie d'administration. Leur âge moyen est de $47,7 \text{ ans} \pm 13$. A l'inclusion, leur pression artérielle systolique moyenne est de $132 \text{ mmHg} \pm 18$ et leur pression artérielle diastolique moyenne est de $79 \text{ mmHg} \pm 8$. L'hémoglobinemie moyenne des malades est à $10,2 \text{ g/dl}$ et le taux de ferritine médian est de 667 ng/ml .

L'objectif principal de l'étude est d'étudier les variations de l'hémoglobine entre l'inclusion et la période d'évaluation. Après un suivi de 43 jours, l'hémoglobine moyenne est de 10,5 g/dl. Nous n'avons pas retrouvé de différence significative entre les deux traitements. Peu d'effets indésirables ont été constatés durant l'étude.

Chez des patients dialysés, le traitement par EPOMAX[®] maintient efficacement l'hémoglobine à la concentration cible et est bien toléré.

Keywords: chronic renal failure, dialysis, human recombinant erythropoietin, anemia, hemoglobin, biosimilar epoetin alfa.

Lien URL: Harzallah A, Zouaghi K, Dridi A, Boubaker K, Beji S, Ayari M, El Younsi F, Moussa FB, Kheder A. Therapeutic efficacy of a biosimilar epoetin alfa in hemodialysis patients. Saudi J Kidney Dis Transpl 2015;26:78-82.

Available from: <http://www.sjkd.org/text.asp?2015/26/1/78/148744>

Or from PubMed: <http://www.ncbi.nlm.nih.gov/pubmed/25579720>.