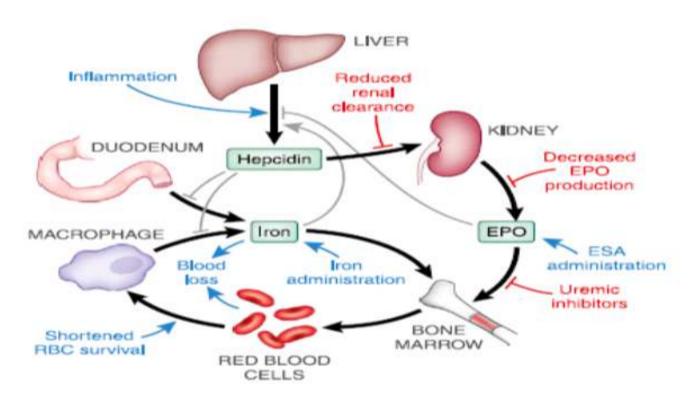


ANFOE

Recombinant Human Erythropoietin Alfa Injection 2000 IU / 4000 IU / 6000 IU / 10000 IU

Anemia in Chronic Kidney Disease:

- The anemia of chronic kidney disease (CKD) is, in most patients, normocytic and normochromic.
- It is principally due to reduced renal erythropoietin (EPO) production and, to a lesser degree, to shortened red cell survival.
- Anemia can develop well before the onset of uremic symptoms due to end-stage renal disease (ESRD). Although anemia due to renal dysfunction generally develops when the glomerular filtration rate (GFR) declines to <30 mL/min, it can be observed in those with higher GFRs.
- If left untreated, the anemia of CKD is associated with several abnormalities. These include deterioration in cardiac function, decreased cognition and mental acuity, fatigue, and other signs and symptoms.
- The primary therapeutic options for the anemia of CKD include red blood cell transfusions, erythropoietin-stimulating agents (ESAs), and, to a much lesser degree, androgens.
- Iron must also be available to support erythropoiesis, so iron supplementation is also an important component of anemia management in patient with anemia of CKD.



- Iron availability is controlled by the liver hormone hepcidin, which regulates dietary iron absorption and macrophage iron recycling from senescent red blood cells.
- In CKD patients (particularly in end stage kidney disease patients on hemodialysis), hepcidin levels have been found to be highly elevated, presumably due to reduced renal clearance and induction by inflammation, leading to iron-restricted erythropoiesis.
- The main reason for the renal anemia is the insufficient secretion of erythropoietin resulted from the decrease in the production by impaired kidney & may also lead to circulating uremic-induced inhibitors of erythropoiesis, shortened red blood cell lifespan, and increased blood loss.

Clinical Evidence:

Clinical Effect of Recombinant Human Erythropoietin (rhEPO) in Anemia of Chronic Renal Failure Patients on Dialysis:

Patients:

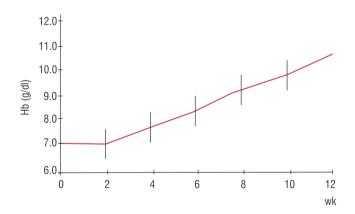
54 Patients with end stage renal failure were recruited who had been on hemodialysis or peritoneal dialysis for more than 3 months and showed renal anemia with $\leq 8g/dl$ of hemoglobin and ≥ 100 ng/ml of serum ferritin

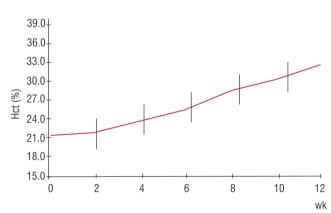
Methods:

- As an initial dose of recombinant human Erythropoietin for hemodialysis patients, 50 unit/kg was administered three times per week by i.v. or s.c. injection after regular dialysis.
- If the patients were dialyzed only for two weeks, weekly dose was divided into the number of dialysis making it 150 unit/kg/week.
- For the patients in peritoneal dialysis, initial 50 unit/kg was administered twice a week.
- As a maintenance dose, in case more than 1.4g/dl of Hb increase occurred within 2 weeks, the dose was reduced by 25 unit/kg weekly.
- If more than 1g/dl of Hb increase was not achieved within first 4 weeks, 50 unit/kg of increase was made to sustain the increasing rate of Hb at more than 0.6g/dl in two weeks and the total amount for administration was controlled not to exceed 225 unit/kg.

Results:

- Hb and hematocrit were improved from $7.11 \pm 0.85g/dl$ and $21.3 \pm 2.6\%$ at baseline to $10.42 \pm 1.31g/dl$ and $31.9 \pm 3.5\%$ at the end of the treatment (p=0.0001), respectively.
- Reticulocyte increased significantly from 0.90 ±0.74% to 2.45 ±0.84% on the 2nd week of the treatment.





Conclusion:

· Recombinant human erythropoietin was efficacious in the treatment of anemia of most of CRF patients

References:

1) I Am Soc Nephrol 23: 1631–1634, 2012 2)The Korean Journal of Nephrology : Vol.19, No.2, 2000





Recombinant Human Erythropoietin Alfa Injection 2000 IU / 4000 IU / 6000 IU / 10000 IU

Description:

The extensive use of EPO and its analogues (erythropoietin- stimulating agents, ESAs) for the purpose of anemia correction has succeeded in reduction of associated morbidity and improvement of functionality, exercise tolerance, cognitive function and overall quality of life. Moreover, significant reduction of cardiovascular (CV) morbidity and mortality has occurred. Anfoe (epoetin alfa) is a 165-amino acid erythropoiesis-stimulating glycoprotein manufactured by recombinant DNA technology. Each 1 mL PFS contains 2000IU, 4000IU, 6000IU or 10,000IU of epoetin alfa.

Indication:

ANFOE has been recommended for the treatment of anemia due to Chronic Kidney Disease (CKD), including patients on dialysis.

Mechanism of action:

ANFOE stimulates erythropoiesis by the same mechanism as endogenous erythropoietin. When administered intravenously, it travels to the bone marrow where it binds to the erythropoietin receptors (EpoR) on the red cell surface and activates a JAK2 cascade to stimulate the production of red blood cells from bone marrow stem cells. The increase in the number of red blood cells delivers more oxygen to all cells in the body, especially muscle cells.

Dosage:

ANFOE dosage for patients with CKD on dialysis:

ANFOE treatment when the hemoglobin level is < 10 g/dl. If the hemoglobin level approaches or exceeds 11 g/dl, reduce or discontinue.

The recommended starting dose for adult patients is 50 to 100 Units/kg three times weekly intravenously or subcutaneously.

For pediatric patients, a starting dose of 50 Units/kg three times weekly intravenously or subcutaneously is recommended.



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