



1725 I Street NW • Suite 510 • Washington, DC 20006  
Tel 202-659-0599 • Fax 202-659-0709 • [www.asn-online.org](http://www.asn-online.org)

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**Contact:** Shari Leventhal: 202-416-0658, [sleventhal@asn-online.org](mailto:sleventhal@asn-online.org)

## **INTRAVENOUS IRON MAY HELP TREAT ANEMIA IN PATIENTS WITH KIDNEY DISEASE**

**Washington, DC (June 4, 2008)** — A new intravenous (IV) iron compound called ferumoxytol shows promising results in the treatment of iron deficiency anemia in patients with chronic kidney disease (CKD), reports a study in the August 2008 issue of *Journal of the American Society of Nephrology* (JASN).

"Ferumoxytol improved hemoglobin and iron stores in study subjects more effectively than oral iron and was well tolerated," commented Dr. Bruce S. Spinowitz, MD, Clinical Professor of Medicine, Weill Medical College of Cornell University. In the study, 304 patients with CKD were randomly assigned to treatment with IV ferumoxytol, two injections within five days, or 21 days of oral iron treatment.

Patients with CKD have a loss of kidney function that, in many cases, progresses to end-stage renal disease requiring dialysis, and can also develop anemia. Anemia means low levels of hemoglobin, which carries oxygen in the blood. "Iron deficiency anemia is a common problem in patients with CKD," Dr. Spinowitz explains. "It is currently undertreated, particularly in the outpatient setting."

After one month, patients treated with ferumoxytol had greater average increases in hemoglobin level than those treated with oral iron, and more ferumoxytol treated patients had a significant 1 g/dL (gram per deciliter) increase in hemoglobin level. Patients in the ferumoxytol group also increased their ferritin levels, an indicator of the body's iron stores.

Ferumoxytol improved hemoglobin and iron levels regardless of whether the patients were being treated with drugs called erythropoiesis-stimulating agents (ESAs). ESAs, which stimulate the bone marrow to produce red blood cells, have been a major advance in the treatment of kidney disease-related anemia. Treatment for CKD-related anemia often requires both iron and ESAs. However, there is ongoing controversy related to the safety, appropriate clinical use, and high costs of ESAs. The treatment of anemia with oral iron has key limitations, including oral iron's limited absorption and gastrointestinal adverse effects (such as nausea and diarrhea) that may affect patient compliance. In the study, patients treated with ferumoxytol had fewer side effects than those treated with oral iron.

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Currently available IV iron products also have limitations, including that they are usually given only in small doses in CKD patients. Ferumoxytol was studied at high doses, which reduced the number of IV injections required. "This is important because limiting venipuncture helps to preserve veins for future hemodialysis vascular access," says Dr. Louis Brenner, Senior Vice President at AMAG Pharmaceuticals, Inc., and a nephrologist at Brigham and Women's Hospital in Boston, MA.

The study results show that ferumoxytol is a potential new treatment for iron deficiency anemia. "This was a pivotal Phase III clinical trial that has been submitted to the Food and Drug Administration as part of a New Drug Application seeking marketing approval for ferumoxytol to treat iron deficiency anemia in patients with CKD," comments Dr. Brenner.

More research is needed to determine whether ferumoxytol can reduce the dosage of costly ESA therapy needed to treat CKD-related anemia. "Our study held ESA dosing stable, therefore, any reductions in ESA dosing that could be achieved with appropriate IV iron repletion in CKD patients with iron deficiency anemia, will require further investigation," Dr. Brenner adds.

Dr. Brenner and co-authors, Drs. Annamaria T. Kausz and Brian J. G. Pereira, are employees of AMAG Pharmaceuticals. Ms. Jovanna Baptista, another contributor to the study, is a former employee of AMAG Pharmaceuticals. Dr. Spinowitz is a member of the Clinical Studies Steering Committee of AMAG Pharmaceuticals.

The study, entitled "Ferumoxytol for Treating Iron Deficiency Anemia in CKD," will be available online at <http://jasn.asnjournals.org/> beginning today and in print in the August issue of JASN.

The American Society of Nephrology (ASN) is a not-for-profit organization of 11,000 physicians and scientists dedicated to the study of nephrology and committed to providing a forum for the promulgation of information regarding the latest research and clinical findings on kidney diseases. ASN publishes JASN, the *Clinical Journal of the American Society of Nephrology* (CJASN), and the *Nephrology Self-Assessment Program* (NephSAP). In January 2009, ASN will launch a newsmagazine.

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