

New medication class may safely and effectively treat anemia

October 22 2015

Investigational drugs that produce effects in the body similar to what occurs at high altitudes may offer a new way to stimulate red blood cell production and treat patients with anemia, according to studies appearing in an upcoming issue of the *Journal of the American Society of Nephrology (JASN)*. The findings may lead to safer alternatives than currently used anemia medications.

Patients with [chronic kidney disease](#) or kidney failure often experience severe degrees of [anemia](#), or low levels of red [blood cells](#), which limits oxygen delivery to tissues. Anemia commonly arises in [patients](#) with kidney dysfunction because the kidneys secrete most of the hormone erythropoietin, which stimulates [red blood cell](#) production. Anemia is assessed by a patient's level of hemoglobin, the component of red blood cells that transports oxygen throughout the body.

Current therapies for anemia include recombinant human erythropoietins, erythropoiesis-stimulating agents (ESAs), and intravenous iron, all of which carry considerable safety concerns. Investigators now report promising results of a new class of oral medications, called hypoxia-inducible factor prolyl hydroxylase inhibitors (HIF-PHIs), to treat anemia in patients with kidney disease. These drugs produce effects in the body similar to what occurs at high altitude, essentially causing the body to make more red blood cells that carry oxygen to where it is needed.

In a phase 2 randomized clinical trial, Anatole Besarab, MD (FibroGen,

Inc.) and his colleagues enrolled 60 dialysis patients who received no iron, oral iron, or intravenous iron while treated with a HIF-PHI called roxadustat (also known as FG-4592) for 12 weeks. Roxadustat increased erythropoietin and concomitantly improved several processes that increased the availability of iron for incorporation into hemoglobin in red blood cells. Roxadustat with only moderate oral iron supplementation corrected anemia (as assessed by patients' hemoglobin levels) as well as roxadustat with intravenous iron. Average hemoglobin increases of 2 g/dl were achieved within 7 weeks in study participants.

"As anemia is associated with an increased risk of cardiac events and death as well as decreased quality of life, the availability of such an oral therapy could change the landscape of treatment of anemia in [kidney failure](#) patients," said Dr. Besarab.

In 2 other phase 2 clinical trials, a team led by Louis Holdstock, PhD and Alexander Cobitz, MD, PhD (GlaxoSmithKline) enrolled 73 nondialysis patients with chronic kidney disease and 83 hemodialysis patients to test the effects of a HIF-PHI called GSK1278863 (0.5mg, 2mg, or 5 mg) compared with control (placebo for the nondialysis study; continuing on recombinant human erythropoietin for the hemodialysis study). In the nondialysis study, GSK1278863 produced dose-dependent effects on hemoglobin, with the highest dose resulting in an average increase of 1 g/dl at week 4. In the hemodialysis study, treatment with GSK1278863 in the 5-mg arm maintained average hemoglobin concentrations after the switch from recombinant human erythropoietin, whereas average hemoglobin decreased in the lower-dose arms.

"This research lays the foundation for future longer-term trials that will examine whether GSK1278863 can manage anemia in patients with CKD with a reduced incidence of cardiovascular events and death," said Dr. Holdstock.

In an accompanying editorial, Colin Lenihan, MD (Stanford University School of Medicine) and Wolfgang Winkelmayr, MD, MPH, ScD (Baylor College of Medicine) noted that the kidney community has been put on high alert by various safety issues with other anemia treatments in the past decade and a half. While they believe that phase 3 clinical trials of HIF-PHIs will help address some of these concerns, the safety of these medications with regard to rare events will require careful postmarketing surveillance after the drugs are approved.

More information: The article, entitled "Roxadustat (FG-4592): Correction of Anemia in Incident Dialysis Patients," will appear online at jasn.asnjournals.org/ on October 22, 2015.

The editorial, entitled "The Dawning of a New Day in CKD Anemia Care?" will appear online at jasn.asnjournals.org/ on October 22, 2015.

Provided by American Society of Nephrology

Citation: New medication class may safely and effectively treat anemia (2015, October 22)
retrieved 2 May 2024 from

<https://medicalxpress.com/news/2015-10-medication-class-safely-effectively-anemia.html>

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