Biosimilar to infliximab shows equivalent safety and efficacy for treating Crohn's disease

December 11 2018

A biosimilar of infliximab, CT-P13, has equivalent safety and efficacy to that of the anti-tumor necrosis factor (TNF) monoclonal antibody for treating Crohn's disease in infliximab-naïve patients. Findings from a comparative equivalence cohort study are published in *Annals of Internal Medicine*.

The TNF inhibitors, including infliximab, have improved the management of inflammatory bowel disease. The U.S. Food and Drug Administration defines biosimilars as "highly similar to the reference product notwithstanding minor differences in clinically inactive components and for which there are no clinically meaningful differences between the biologic product and the reference product in terms of safety, purity, and potency of the product." CT-P13 is a biosimilar to infliximab that has demonstrated efficacy and safety for some inflammatory arthritides and was approved for Crohn's disease on that basis, without specific studies examining its effects in Crohn's disease.

Researchers from Caisse Nationale de I'Assurance Maladie studied a French nationwide database to compare the effectiveness and safety of CT-P13 and the reference product (infliximab). The study included 5,050 infliximab-naïve patients who started treatment with infliximab (n = 2,551) or CT-P13 (n = 2,499). The researchers found that CT-P13 had equivalent efficacy to infliximab and no difference was observed in terms of safety outcomes. Based on these findings, the researchers

suggest that the choice between the two products could be based solely on cost.

The authors of an accompanying editorial from the University of Copenhagen Herlev Hospital point out that the introduction of biosimilars has resulted in cost savings for patients. Further economic benefits may also be realized as access to treatment increases. Regardless, the authors stress that full transparency is a must when patients are switched to or begin treatment with a biosimilar. Health care professionals must be proactive in increasing patients' confidence by providing evidence-based information from the growing experience with biosimilars.

More information: Study: http://annals.org/aim/article/doi/10.7326/M18-1512
Editorial: http://annals.org/aim/article/doi/10.7326/M18-3060

Provided by American College of Physicians

Citation: Biosimilar to infliximab shows equivalent safety and efficacy for treating Crohn's disease (2018, December 11) retrieved 27 April 2024 from https://medicalxpress.com/news/2018-12-biosimilar-infliximab-equivalent-safety-efficacy.html

This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.