

IBD

Sargramostim for corticosteroid-dependent Crohn's disease

New data reveal that sargramostim can induce corticosteroid-free remission in patients with corticosteroid-dependent Crohn's disease. "The absolute difference in remission rates in favor of sargramostim was relatively modest (13.7%), but this ... is clinically relevant given the limited ... options available to these patients," says John Valentine, lead investigator.

Granulocyte-macrophage colony-stimulating factor (GM-CSF) is thought to have beneficial effects on the intestinal innate immune barrier. The efficacy of sargramostim—a recombinant, human GM-CSF—has been shown for moderate to severe, active Crohn's disease, but this was in the absence of corticosteroids, immunosuppressants or anti-TNF agents.

In this randomized, double-blind, placebo-controlled, phase II study, sargramostim induced remission and allowed corticosteroids to be discontinued in patients with active, corticosteroid-

dependent Crohn's disease. Patients receiving higher corticosteroid doses were less likely to respond to treatment, which suggests that corticosteroids may interfere with sargramostim's beneficial action. The drug was associated with adverse events, but most were mild, and the level of drug tolerance was acceptable.

Valentine believes there is a role for sargramostim in the treatment of Crohn's disease, but says "...more study is needed ... to determine how GM-CSF treatment benefits patients ... and to further document safety." He also speculates that sargramostim might be more beneficial for patients with a shorter duration of disease.

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Original article Valentine, J. F. *et al.* Steroid-sparing properties of sargramostim in patients with corticosteroid-dependent Crohn's disease: a randomised, double-blind, placebo-controlled, phase 2 study. *Gut* **58**, 1354–1362 (2009).