

Drug improves remission of Crohn disease among children and adolescents

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Among children and adolescents with Crohn disease not responding to treatment, use of the drug thalidomide resulted in improved clinical remission after 8 weeks of treatment compared with placebo, according to a study appearing in the November 27 issue of *JAMA*.

As many as 1.2 million people in Europe and more than half a million in the United States are estimated to have Crohn disease, a [chronic inflammatory disease](#) involving the digestive system. Its incidence is increasing globally. "About 25 percent of people with Crohn disease develop symptoms as children, and these cases are generally more severe than adult-onset cases. Resistance or intolerance to therapy is common in children with Crohn disease, with up to approximately 18 percent of cases requiring surgery within 5 years from disease onset," according to background information in the article. Thalidomide is a drug used to treat inflammatory diseases of the skin and [mucous membranes](#). Observational studies on [thalidomide](#) in patients with Crohn disease have reported encouraging results.

Marzia Lazzerini, Ph.D., of the Institute for Maternal and Child Health, Trieste, Italy and colleagues evaluated the efficacy and adverse effects of thalidomide in inducing clinical remission in children and adolescents with refractory (not responding to treatment) Crohn disease. The study included 56 children and was conducted August 2008-September 2012 in 6 pediatric care centers in Italy. Children were randomized to thalidomide or placebo once daily for 8 weeks. The primary measured outcomes were a reduction in the Pediatric Crohn Disease Activity Index

(PCDAI) score of ≥ 25 percent or ≥ 75 percent at weeks 4 and 8 (clinical remission). Nonresponders to placebo received thalidomide for an additional 8 weeks. All responders continued to receive thalidomide for an additional minimum 52 weeks.

The researchers found that clinical remission was achieved by more children treated with thalidomide (13/28 [46.4 percent] vs. 3/26 [11.5 percent]). Responses were not different at 4 weeks, but greater improvement was observed at 8 weeks in the thalidomide group. Of the nonresponders to placebo who began receiving thalidomide, 11 of 21 (52.4 percent) subsequently reached remission at week 8. Overall, 31 of 49 [children](#) treated with thalidomide (63.3 percent) achieved clinical remission, and 32 of 49 (65.3 percent) achieved 75 percent response.

Average duration of clinical [remission](#) in the thalidomide group was 181 weeks vs. 6.3 weeks in the [placebo group](#).

"These findings require replication to definitively determine the utility of this treatment," the authors conclude.

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