

Study finds that vioxx reduces the risk of colorectal polyps

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A researcher from Dartmouth reports the results of a clinical trial that shows that the cyclooxygenase-2 (COX-2) inhibitor rofecoxib (VIOXX®) reduces the risk of colorectal adenomas, or polyps. Polyps are benign tumors that are precursors to colon cancer, and they are often found in older adults.

The results of the study appeared online on August 30 at the American Gastroenterological Association website [www.gastro.org] in advance of being published in the journal, Gastroenterology. Extensive data have suggested previously that aspirin and non-selective nonsteroidal anti-inflammatory drugs (NSAIDs) could reduce colon cancer risk, and this study now demonstrates a similar effect for VIOXX®. The study is at: [www.gastro.org/user-assets/Doc ... Randomized_Trial.pdf](http://www.gastro.org/user-assets/Doc...Randomized_Trial.pdf)

"These are exciting findings," says Dr. John Baron, the lead author of the paper and a professor at Dartmouth Medical School, who has been studying chemoprevention of colorectal cancer for more than twenty years. "They show once again the potential for NSAIDs to interfere with the development of cancer in the colon and rectum."

This study, called the APPROVe (Adenomatous Polyp Prevention on VIOXX®) study, was a randomized, placebo-controlled, double-blind trial conducted by Merck Research Laboratories. The study involved 108 sites in the United States and abroad and followed 2,587 patients with a recent history of confirmed colorectal adenomas. After removal of all polyps, the subjects were randomized to receive daily placebo or 25 mg

rofecoxib on a daily basis. The primary endpoint was to analyze all adenomas diagnosed during the three-year treatment period based upon colonoscopies conducted one year and three years after baseline.

In addition, an extension to the APPROVe study was conducted to assess recurrence of adenomas in the year following the end of the three years' treatment through a colonoscopy at year four. Previous randomized studies have also shown that COX-2 inhibitors can lower the risk of polyps in patients with a rare genetic syndrome called familial adenomatous polyposis (FAP), but this is the first to illustrate the effect in the broad population of people at risk for colorectal cancer.

Patients taking rofecoxib had a lower recurrence rate of adenomas than those taking placebo (41 percent vs 55 percent; p

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