

Cancer drug regimen linked to high death rates

A recently approved chemotherapy regimen consisting of a trio of drugs has been linked to an usually high death rate.

In each of two studies conducted by the National Cancer Institute, 14 deaths were reported within 60 days of the start of treatment, compared with just five deaths in control groups using other treatments. The Mayo Clinic in Rochester, Minn., was the lead research site in one of the trials.

In what many health advocates would categorize as a supreme case of understatement, Michael J. O'Connell, M.D., deputy director for clinical affairs at the Mayo Clinic Cancer Center noted, "Caution needs to be exercised when this particular chemotherapy combination is used for treating patients with colorectal cancer."

The danger was deemed so severe that the *New England Journal of Medicine*, which wasn't due to publish the report for another month, released the information early. In addition, the trials were halted to prevent further damage or deaths to the study's participants.

The drugs -- irinotecan, fluorouracil, and leucovorin -- recently became the "treatment of choice" for patients with advanced colorectal cancer.

The drug combination had been approved by the FDA.

SOURCES: "Recommendation for Caution with Irinotecan, Fluorouracil, and Leucovorin for Colorectal Cancer," *New England Journal of Medicine*, June 21, 2001.

"Colorectal Cancer Clinical Trial N9741: Questions and Answers," Mayo Clinic, Rochester, Minn.