

New recommendations issued for use of cetuximab in colon cancer therapy

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In a report published in the July 2010 issue of the *American Society for Clinical Oncology Post*, new recommendations on the use of the drug cetuximab have been issued after officials halted enrollment in a phase III clinical trial in patients with spread of colon cancer into regional lymph nodes whose tumors had been surgically removed.

Based on earlier studies, cetuximab is now indicated for treatment of patients with advanced [colorectal cancer](#) whose tumors do not have a mutation in the KRAS gene. KRAS is one of a series of genes along a pathway that can lead tumors cells to grow, divide and evade signals that shut the cells down causing their death. Based on the results in advanced disease, researchers had hoped to see similar benefits when cetuximab was added to a standard chemotherapy regimen in earlier stages of colon cancer. However, ongoing analysis during the clinical trial found that patients receiving the combination therapy had no significant improvement in survival compared to standard therapy.

Cetuximab is a monoclonal antibody that inhibits epidermal [growth factor receptor](#) (EGFR) - a cell signaling pathway that contributes to [tumor growth](#). The drug is given by intravenous infusion for treatment of metastatic colorectal cancer and [head and neck cancer](#). Previously, researchers found that patients with a mutated KRAS gene - about 40 percent of those with metastatic colon cancer - do not respond to the EGFR inhibitors currently in use.

However, the genetic test for KRAS mutation was not standard until this

trial was well underway. Patients enrolled before KRAS testing were segmented from those in the rest of the study and analyzed separately, said Richard Goldberg, MD, chief of the division of hematology/oncology at the UNC-Chapel Hill School of Medicine, who presented the results for this group of patients.

"We expected that patients with the genetic mutation would not respond to cetuximab, and that is what we found," said Goldberg, who is also physician-in-chief of the N.C. Cancer Hospital.

"However, even the patients in the study whose tumors did not harbor the KRAS mutation did not benefit significantly from the combination therapy and the standard treatment proved to have the best results. We also found that the [combination therapy](#) was more toxic and the side effects of treatment - especially in older patients - negatively impacted their ability to complete the standard treatment," he added.

The researchers issued a recommendation that [cetuximab](#) should not be used in patients with stage III [colon cancer](#). It remains a valuable tool in treating patients with advanced colorectal cancers whose tumors do not harbor a KRAS mutation and can either be administered as a single agent or with chemotherapy.

Provided by University of North Carolina School of Medicine

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