

# SOUTHWESTERN NEWS

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## UT SOUTHWESTERN STUDY USES COMMON COLD VIRUS FOR GENE THERAPY TO TREAT HEAD AND NECK CANCERS

DALLAS – October 28, 1998 – Patients with advanced head and neck cancer that hasn't improved with surgery, radiation or chemotherapy may benefit from an experimental therapy available at UT Southwestern Medical Center at Dallas.

Physicians in the Department of Otorhinolaryngology have begun injecting a genetically altered adenovirus, one of the viruses that cause the common cold, directly into the tumors of patients with head and neck cancer in an attempt to kill the cancer cells but preserve normal ones.

The unconventional treatment has slowed tumor growth in studies involving cell cultures and a mouse model. Now UT Southwestern is one of a handful of sites nationwide trying to measure how well human tumors respond to the treatment. The findings will help researchers decide whether to expand the study to a more widespread clinical trial.

"For this study, we are treating head-and-neck-cancer patients who have really exhausted their other options," said Dr. Carol Bier-Laning, assistant professor of otorhinolaryngology. "The goal is to gather information for the future, though the patients may improve. We have seen patients who have little or no response to the treatment, and we have seen some results that are very encouraging."

The therapy is based on understanding the role of the *p53* gene, a tumor suppressor that responds to damage in a cell's deoxyribonucleic acid (DNA) by activating either a pathway that halts cell division until the DNA damage has been repaired or a pathway to apoptosis, or cell suicide. But half of human cancers -- and the majority of head and neck cancers -- have mutated *p53* genes that are ineffective.

"We inject the tumor with an adenovirus that contains *p53* that has been genetically

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## **HEAD and NECK – 2**

engineered so it cannot replicate," said Bier-Laning, a co-principal investigator for the study at UT Southwestern. "The virus spits DNA into the cell, and the cell takes it up and begins producing the *p53* gene. The hypothesis is that if we give the cells normal *p53*, it will help control the cancer."

Although the treatment may be effective against other cancers, this trial involves only head and neck cancers, which are easy to access for injection.

Patients who qualify for the study will receive three injections of the virus in three days, followed by a 28-day rest, then another round of injections. Patients whose tumors stabilize or grow less than 25 percent may be eligible for up to four more cycles of injections.

"This treatment isn't yet a mainline therapy to cure the cancer, but maybe it will return the cancer cells to a more normal profile," Bier-Laning said. "It's exciting because this gene therapy gives us a fourth prong in our fight against head and neck cancer."

Introgen Therapeutics, Inc., developed and manufactures the genetically engineered adenovirus used in the study. Introgen collaborates with Rhône-Poulenc Rorer Pharmaceuticals for the clinical development and commercialization of the *p53* drug. Others from UT Southwestern's head-and-neck-surgery unit involved in the study are Dr. John Truelson, associate professor of otorhinolaryngology and the study's co-principal investigator; Dr. Robert Sinard, assistant professor of otorhinolaryngology; and research nurse Sandra Neal.

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