## SOJTHWESTERN NEWS

Media Contact: Amy Shields 214-648-3404 amy.shields@utsouthwestern.edu

## NIH AWARDS UT SOUTHWESTERN \$1.95 MILLION TO STUDY NEW TREATMENTS FOR SERIOUS HIV-DRUG SIDE EFFECTS

DALLAS – Oct. 29, 2002 – A class of drugs known as protease inhibitors has dramatically improved the long-term survival of HIV-infected patients, but these drugs also pose a serious side effect called lipodystrophy, which can cause extremely high cholesterol and diabetes.

Lipodystrophy, which is characterized by the loss of body fat from the face, arms and legs, is also associated with an increased prevalence of insulin resistance and extremely high triglyceride levels.

UT Southwestern Medical Center at Dallas has received a \$1.95 million grant from the National Institutes of Health to study novel treatments for lipodystrophy. The disorder affects nearly 50 percent of HIV-infected patients who have taken protease inhibitors for more than a year. The Joint United Nations Programme on HIV/AIDS estimated in 2001 that 40 million people were infected with HIV.

"Patients who take protease inhibitors have their HIV infection under control, but they are developing another severe metabolic disorder at the same time," said Dr. Abhimanyu Garg, principal investigator of the five-year study and professor of internal medicine. "It's a very challenging task to treat these patients because it is essential for them to take these medications to control the virus."

Physicians first noticed the loss of body fat associated with the lipodystrophy syndrome in HIV-infected patients in 1997, said Garg.

Instead of treating the metabolic abnormalities with cholesterol-lowering drugs, which can interfere with the HIV medications and may cause serious side effects, Garg and his collaborators will evaluate three low-risk therapeutic measures in HIV-infected patients who have been on protease inhibitors for at least one year. Study participants will consume a diet high in monounsaturated fat, participate in a supervised aerobic exercise regimen and will take dietary supplements including fish oils and the plant-based margarine Benecol.

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"Most of the therapies that have been studied are accompanied by high-risk side effects, including giving the patients cholesterol-lowering medication," said Garg. "Another strategy includes replacing their protease inhibitors with an alternative HIV medication, but this option may not control the virus as well, and may not improve metabolic abnormalities.

"We are trying to see how safely we can lower their cholesterol and improve their insulin resistance. All of the therapies that we will be evaluating in this study have been very beneficial in patients with diabetes and insulin resistance."

The researchers will also evaluate the effectiveness of leptin therapy, an investigational drug, which has been shown to drastically reduce triglyceride and glucose levels in patients with inherited and other types of acquired lipodystrophies. Leptin is a protein produced by fat cells and is nearly absent in patients with generalized lipodystrophies.

This is the second NIH grant that Garg has received to study lipodystrophy in HIV patients. In 1999 Garg received a \$2.7 million grant to study the underlying basis and complications of the syndrome. In that study, which is still in progress, the researchers are recruiting HIV-infected patients who have never taken HIV medications.

For more information about the new study or the ongoing study call 214-648-9296.

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