(2) Non-Technical Abstract;

PURPOSE AND BACKGROUND

Dr. Principal Investigator is participating in a multi-center research trial sponsored by Berlex Laboratories Inc. to find out if 1) whether gene therapy using Ad5.1-FGF4, an investigational/experimental procedure, can be safely administered and 2) whether such experimental therapy can stimulate the growth of new blood vessels in the heart and benefit patients with angina pectoris. Angina pectoris is caused by narrowing of the blood vessels to the heart. You have been asked to participate in this trial because you have angina pectoris. The vascular growth treatment called AdS.l-FGF4 is an experimental treatment. It has been designed to provide gene therapy with the FGF4 gene to cause new blood vessel growth and relieve angina pectoris. Gene therapy refers to a new form of therapy in which genes are introduced into cells and the cells then produce the specific protein that the gene directs, in this case a protein known as fibroblast growth factor 4 (FGF4).

The gene is carried into the heart cells by a modified virus. This modified virus (Ad5.1) has been constructed from adenovirus, a similar virus which sometimes causes the common cold. The virus has been modified in a way so that it cannot multiply and thus cannot cause infection. The FGF4 gene has been added to the modified adenovirus. The FGF4 gene is being used because FGF4 has been found to stimulate the growth of new blood vessels. In an experimental animal model in pigs that mimics human disease it was found that therapy with Ad5.l-FGF4 resulted in production of FGF4 and improved blood flow to the heart to relieve an experimentally induced condition equivalent to angina pectoris.

You are being asked to participate in this study because during times of stress, your heart has insufficient blood flow, resulting in angina pectoris. Your active participation in this study will last about 12 months. Approximately 375 patients will be enrolled in this trial at up to 80 centers throughout the US and UK.