

(2) non-technical abstract;

PURPOSE AND BACKGROUND

Dr. Principal Investigator is participating in a multi-center research study sponsored by Berlex Laboratories Inc., to find out:

1. Whether gene therapy using Ad5FGF-4 can be safely administered.
2. Whether such therapy will improve blood supply to the heart and benefit patients with angina pectoris by stimulating the growth of new coronary blood vessels.

Angina pectoris is the medical term used to describe the discomfort due to a temporary inadequacy of blood supply to the heart due to narrowing of the blood vessels that supply blood to the heart. Gene therapy refers to a new form of treatment in which a gene is injected into the body where it directs the production of a specific protein expressed by that gene. The gene in this experimental treatment is the fibroblast growth factor 4 gene (FGF4). It directs the production of the fibroblast growth factor 4 protein, which causes development of new blood vessels. The FGF4 gene is attached to a carrier called Ad5, which is a changed form of the virus that causes the "common cold". The adenovirus is changed by taking out the area that allows the virus to reproduce; so that the virus does not multiply inside the body. The virus-gene combination is called Ad5FGF-4. This is injected in a single dose into the coronary arteries, which are the vessels that supply blood to the heart.

Experimental studies in pigs that have had artificially induced angina have shown that injection of the FGF4 gene attached to the adenovirus into the coronary arteries caused production of the FGF4 protein, resulting in growth of new coronary blood vessels and improvement in blood supply to the heart. These studies also showed that the gene expression is temporary and the new blood vessel formation is confined to the heart.

In an ongoing human study the effects of this gene therapy have been studied. The data collected so far shows that it is well tolerated.

You are being asked to participate in this study because during times of physical stress, your heart has insufficient blood supply resulting in angina. Your active participation in this study could last up to four months followed by additional follow up at 3, 6, and 12 months.