

Clinical Trial Evaluates Protein's Ability to Grow New Blood Vessels, Reduce Angina Pain

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As part of a multi-center clinical trial, UC San Diego Medical Center is evaluating the safety and effectiveness of a potential new way to treat angina - by injecting a protein that stimulates the growth of new oxygen-rich blood vessels directly into the heart. Angina is a debilitating form of chest pain caused by coronary artery disease that affects more than nine million Americans.

"This phase two clinical trial is testing whether or not a growth factor, injected into the heart muscle, is a safe way to initiate the growth a new network of blood vessels," said Anthony DeMaria MD, principal investigator of the trial and director of the Sulpizio Family Cardiovascular Center at UC San Diego Medical Center. "With a new source of blood circulation, the goal is to reduce or eliminate attacks of angina."

Described as squeezing pain or pressure, angina is caused by an insufficient blood supply to the heart. For some patients, the placement of a stent, or bypass surgery, may restore blood flow. Growth factor, a naturally occurring protein capable of stimulating cellular growth and proliferation, may one day offer a third treatment option for this condition.

This placebo-controlled, double-blind study will evaluate the safety and tolerability of three different doses of a protein called human recombinant fibroblast growth factor-1. Eligible patients include males and females between the ages of 25 and 75 with a minimum three-month history of angina. The angina must be triggered by physical exertion and relieved by rest or nitroglycerin.

Mkrtich Bandikian, the first California patient to participate in this trial, had quadruple bypass surgery more than a decade ago. He now suffers from angina if emotionally upset or during mild exercise such as walking.

"I volunteered for the study for two reasons," said Bandikian. "Number one, I did this for myself. I like the idea of addressing the angina without surgery. Number two, if the doctors try this on me, and if the study helps another human being, why not let them try?"

"My hope is that the angina pain will go down and that I will not have to take as much medication," added Bandikian. "I hope to be able to exercise again to raise my good cholesterol level."

Before the protein is injected into the patient, a three-dimensional color-coded map is made of the patient's heart using a technology called the NOGA XP Cardiac Navigation System. Guided by the map, Nabil Dib, MD, co-investigator of the trial, performs a one-hour procedure in which a catheter is threaded through the leg's femoral artery and up into the heart. The protein is then injected into areas of the left ventricle that exhibit decreased blood flow.

Patients who participate in this study are followed for a period of one year. Evaluations include exercise stress tests, nuclear imaging, electrocardiograms, and blood work.

According to the American Heart Association, nearly 10 million people in the United States suffer from angina and an estimated 500,000 new cases of stable angina occur each year. Angina is a sign that someone is at increased risk of heart attack, cardiac arrest or sudden cardiac death.

This clinical trial is sponsored by CardioVascular BioTherapeutics. Up to eight subjects will be recruited at UC San Diego Medical Center and more than two hundred nationwide.

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