

Non-Technical Abstract:

This study is designed to develop a new approach for the treatment of recurrent stable angina pectoris in female patients who are not candidates for traditional mechanical revascularization and who are on optimal drug therapy. There are over 13 million people in the United States with symptomatic coronary heart disease and since 1984 more women have died of cardiovascular disease than men. Over 6 million Americans suffer from angina pectoris, with about 400,000 new cases diagnosed each year. New therapeutic options are needed to meet the demands of these patients who have recurrent chronic angina even following surgery and/or other cardiac interventions for revascularization. Furthermore, an anti-ischemic therapy for control of anginal symptoms is becoming a particularly pressing need in women.

Cardium is studying the effects of an investigational gene therapy product called Ad5FGF-4 in patients with exercise-induced chest pain. It has not been approved by the FDA. The purpose of this study is to test the effects (good and bad) of the study product and whether or not it improves myocardial ischemia and associated angina symptoms.

Ad5FGF-4 has been evaluated in four prospective, randomized, placebo-controlled multi-center clinical studies. The safety data base includes 663 patients (213 placebo and 450 Ad5FGF-4) who have been followed for a period of over 1,700 patient years. There have not been any cases of clinical myocarditis, evidence of an increase in heart failure, reports of pathological angiomas or retinal neo-angiogenesis. Long-term follow-up safety data collection to assess the risk of delayed adverse events following intracoronary delivery of Ad5FGF-4 is ongoing for AGENT-3 and AGENT-4. In the current follow-up database from the four AGENT studies, there have been no statistically significant differences in the incidence of adverse events during long-term follow-up.