

Abstract

This protocol has been designed to investigate arterial gene transfer of naked DNA encoding for the 165-amino acid isoform of the VEGF-1 (VEGF A) gene as an adjunct to PTCA. The protocol has the following two objectives.

Objective #1: is to determine the safety of coronary gene transfer of phVEGF₁₆₅ to accelerate re-endothelialization (rET) following percutaneous transluminal coronary angioplasty (PTCA) in patients with stenotic native coronary arteries.

Objective #2: is to obtain preliminary data regarding bioactivity of coronary gene transfer of phVEGF₁₆₅ for prevention of restenosis.

The protocol outlined in this Investigational New Drug Application has been designed as a Phase I single-site, dose-escalating study of intra-arterial (IA) phVEGF₁₆₅ gene transfer in patients undergoing non-emergent native coronary artery PTCA and deployment of a single 13-28 mm intracoronary endovascular stent. Patient Eligibility includes Males or Females \geq 21 years with angiographic evidence of coronary artery disease in a vessel \geq 2 mm indicated for treatment by PTCA and deployment of a single 13-28mm endovascular stent. Up to 12 patients will be enrolled and treated for this study over a period of 1 year.