

Non-Technical Abstract

CLI is the most severe manifestation of PAD in the legs with both high societal and individual patient costs. Current treatment options are inadequate, particularly for patients who are not candidates for replacement of blood vessels by surgery (revascularization), or in whom this procedure has failed. Even in patients who undergo surgical procedures to repair damaged arteries, there remains a great need to improve the clinical outcome of limb preservation. Therapeutic Angiogenesis is the ability to promote the growth of new blood vessels for the treatment of disorders of inadequate tissue perfusion. The HGF Plasmid has demonstrated potential for promoting new blood vessel growth in damaged tissue based on in vitro, animal, and clinical models.

AnGes-MG, Inc. has begun investigating hepatocyte growth factor (HGF) as a potential therapy for patients with PAD. HGF has potent angiogenesis activity that may result from a combination of direct effects muscle and endothelial cells. HGF shares many similarities to another gene therapy in development, VEGF, but may lack the side effect of VEGF which forms leaky blood vessels and bruising.

AnGes will undertake a Phase I/II trial to evaluate the effectiveness of HGF on patients with CLI. AnGes will conduct this study at approximately 20 sites around the country. The trial will evaluate different doses and several dosing regimens to determine the best approach to treatment of patients in the future with HGF. The trial will include approximately 110 patients and will take approximately 2 years to conduct. AnGes will do everything possible to ensure the safety and privacy of all patients involved in this trial.