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Abstract

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High doses of vascular endothelial growth factor 165 safely, but transiently, improve myocardial perfusion in no-option ischemic disease.

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Abstract

Gene therapy can induce angiogenesis in ischemic tissues. The aim of this study was to assess safety, feasibility, and results, both clinical and on myocardial perfusion, of gene therapy in refractory angina. This was a phase III, prospective, temporal-controlled series, clinical trial. Thirteen patients were maintained for minimum 6 months under optimized clinical management, and then received intramyocardial injections of 2000 µg plasmid vascular endothelial growth factor 165 and were followed by single-photon emission computed tomography (SPECT), treadmill tests, Minnesota quality of life questionnaire (QOL), and New York Heart Association (NYHA) functional plus Canadian Cardiovascular Society (CCS) angina classifications. There were no deaths, early or late. During the optimized clinical treatment, we observed worsening of rest ischemia scores on SPECT ($p < 0.05$). After treatment, there was a transitory increase in myocardial perfusion at the third-month SPECT under stress (pre-operative [pre-op] 18.38 ± 7.51 vs. 3 months 15.31 ± 7.30 ; $p < 0.01$) and at the sixth month under rest (pre-op 13.23 ± 7.98 vs. 6 months: 16.92 ± 7.27 ; $p < 0.01$). One year after, there were improvements in treadmill test steps (pre-op 2.46 ± 2.07 vs. 12 months 4.15 ± 2.23 ; $p < 0.01$) and oxygen consumption (pre-op 7.66 ± 4.47 vs. 12 months 10.89 ± 4.65 ; $p < 0.05$), QOL (pre-op 48.23 ± 18.35 vs. 12 months 28.31 ± 18.14 ; $p < 0.01$) scores, and CCS (pre-op 3 [3-3.5] vs. 12 months 2 [1-2.5]; $p < 0.01$) and NYHA (pre-op 3 [3-3] vs. 2 [2-2] vs. 12 months 2 [1-2]; $p < 0.01$) classes. Gene therapy demonstrated to be feasible and safe in this advanced ischemic cardiomyopathy patient sample. There were improvements in clinical evaluation parameters, and a transitory increase in myocardial perfusion detectable by SPECT scintigraphy.

CLINICAL TRIAL REGISTRATION: [NCT00744315](http://clinicaltrials.gov/NCT00744315) <http://clinicaltrials.gov/>

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