

Type of cell therapy does not improve walking ability for patients with peripheral artery disease

November 18 2013

Joseph Poole, M.D., Ph.D., of the Emory University School of Medicine, Atlanta, and colleagues studied whether therapy with granulocyte-macrophage colony stimulating factor (GM-CSF), an agent that functions as a white blood cell growth factor, would improve walking performance in patients with symptomatic peripheral artery disease (a form of vascular disease in which there is partial or total blockage of an artery, usually one leading to a leg or arm).

"Peripheral artery disease (PAD) affects more than 8 million individuals in the United States. Although exercise, smoking cessation, antiplatelet therapy, cilostazol [a medication for PAD], statins, and revascularization are used to treat PAD, men and women with PAD have significantly greater functional impairment and faster functional decline than those without PAD. Stem and progenitor cell (PC) therapy that promotes neoangiogenesis [formation of blood vessels] is an emerging treatment modality in PAD," according to background information in the article. Progenitor cells are involved in vascular repair and regeneration.

The phase 2, placebo-controlled study included 159 patients with intermittent claudication (pain in <u>leg muscles</u>, aggravated by walking and caused by an insufficient supply of blood). Participants were randomized to received 4 weeks of subcutaneous (under the skin) injections of GM-CSF (leukine), 3 times a week (n = 80), or placebo (n = 79).



The researchers found that therapy with GM-CSF did not improve treadmill walking time, a measure of PAD severity at 3-month follow-up. "The improvement in a subset of secondary outcomes observed with GM-CSF suggests that GM-CSF may warrant further study in patients with claudication. In addition, further investigation is needed to investigate the variability of responsiveness to GM-CSF and its clinical significance."

More information: doi:10.1001/jama.2013.282540

Provided by The JAMA Network Journals

Citation: Type of cell therapy does not improve walking ability for patients with peripheral artery disease (2013, November 18) retrieved 15 January 2023 from https://medicalxpress.com/news/2013-11-cell-therapy-ability-patients-peripheral.html

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