

# Clinical trials of cell-based therapies for peripheral vascular diseases in all type of patients

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## 1 gene transfer

Trial	Treatments	Patients	Trials design and methods
<b>AdVEGF121 vs placebo</b>			
<b>RAVE (Rajagopalan) , 2003</b> n=NA follow-up: 12 weeks	adenoviral vascular endothelial growth factor (VEGF) gene transfer (AdVEGF121) versus placebo	subjects with unilateral exercise-limiting intermittent claudication during 2 qualifying treadmill tests, with peak walking time between 1 to 10 minutes	double blind
<b>Del-1 vs placebo</b>			
<b>DELTA (Grossman) , 2007</b> n=188/188 follow-up: 90 days	plasmid encoding the angiomatrix protein Del-1 in conjunction with poloxamer 188 versus placebo (poloxamer 188 )	patients with bilateral intermittent claudication and peak walking time (PWT) between 1 and 10 minutes on 2 qualifying treadmill tests	double blind
<b>phVEGF165 vs placebo</b>			
<b>Kusumanto , 2006</b> n=27/27 follow-up: 100 days	intramuscular administration of phVEGF165 (vascular endothelial growth factor gene-carrying plasmid) versus placebo	patients with diabetes mellitus and critical limb ischemia	double blind
<b>rFGF-2 vs placebo</b>			
<b>TRAFFIC (Lederman) , 2002</b> n=127/63 follow-up: 90 days	rFGF-2 (30 microg/kg) 1 or 2 doses versus placebo	patients with intermittent claudication caused by infra-inguinal atherosclerosis	double blind
<b>VEGF gene vs placebo</b>			
<b>Makinen , 2002</b> n=35/19 follow-up: 3 months	VEGF-adenovirus or VEGF plasmid versus placebo	patients with chronic lower-limb ischemia and atherosclerotic infrainguinal occlusion or stenosis undergoing percutaneous transluminal angioplasty	double blind

## References

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**Kusumanto, 2006:**

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**TRAFFIC (Lederman), 2002:**

Lederman RJ, Mendelsohn FO, Anderson RD, Saucedo JF, Tenaglia AN, Hermiller JB, Hillegass WB, Rocha-Singh K, Moon TE, Whitehouse MJ, Annex BH Therapeutic angiogenesis with recombinant fibroblast growth factor-2 for intermittent claudication (the TRAFFIC study): a randomised trial. *Lancet* 2002;359:2053-8 [[12086757](#)]

**Makinen, 2002:**

Mkinen K, Manninen H, Hedman M, Matsi P, Mussalo H, Alhava E, Yl-Herttuala S Increased vascularity detected by digital subtraction angiography after VEGF gene transfer to human lower limb artery: a randomized, placebo-controlled, double-blinded phase II study. *Mol Ther* 2002;6:127-33 [[12095313](#)] [10.1006/mthe.2002.0638](#)

## 2 About TrialResults-center.org

TrialResults-center is an innovative knowledge database that collects the results of RCTs and provides dynamic interactive systematic reviews and meta-analysis in the field of all major heart and vessels diseases.

The TrialResults-center database provides a unique view of the treatment efficacy based on all data provided directly from clinical trial results, offering a valuable alternative to personal bibliographic search, published meta-analysis, etc. Furthermore, it would allow comparing easily the various concurrent therapeutic for the same clinical condition.

Rigorous meta-analysis method is used to populate TrialResults-center: widespread search of published and non published trials, study selection using pre-specified criteria, data extraction using standard form.

TrialResults-center is continually updated on a weekly basis. We continually search all new results (whatever their publication channel) and these news results are immediately added to the database with a maximum of 1 week.

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