Clinical trials of cell-based therapies for coronary artery disease in all type of patients

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1 cellular therapy

Trial	Treatments	Patients	Trials design and methods
Skeletal Myoblast Transplantation vs placebo			
Genzyme SMC00202 *ongoing* [NCT00102128] n=NA follow-up:	Cultured Autologous Skeletal Myoblast Transplantation versus placebo	patient with prior myocardial infarction and referred for CABG	Parallel groups double blind

References

Genzyme SMC00202, :

2 gene therapy

Trial	Treatments	Patients	Trials design and methods
VEGF gene transfer vs control			
REVASC (Stewart) , 2006 n=NA follow-up:	AdVEGF121 gene transfer with epicardial injection at minithoracotomypj versus control	patients with severe angina due to coronary artery disease and no conventional options for revascularization	open
fibroblast growth factor gene vs placebo			
AGENT 3 and 4 pooled n=NA follow-up:	-	-	
AGENT-1 (Grines) , 2002 n=NA follow-up:	-	-	
AGENT-2 (Grines) , 2003 n=NA follow-up:	-	-	

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Trial	Treatments	Patients	Trials design and methods
AGENT-3 [NCT00346437] n=NA follow-up:	Ad5FGF-4 (replication deficient, E1A/E1Bdeleted, human adenovirus serotype 5 with human FGF-4 gene insert: alferminogene tadenovec versus placebo	-	
AGENT-4 [NCT00185263] n=NA follow-up:	Ad5FGF-4 (replication deficient, E1A/E1Bdeleted, human adenovirus serotype 5 with human FGF-4 gene insert: alferminogene tadenovec versus placebo	-	
AWARE [NCT00438867] n=NA follow-up:	intracoronary infusion of Ad5FGF-4 versus placebo	Female Patients With Stable Angina Pectoris Who Are Not Candidates for Revascularization	double blind
gene therapy vs placebo			
EUROINJECT-ONE (Gyngysi) , 2005 n=NA follow-up:	percutaneously via NOGA-Myostar injectionsof plasmid encoding plasmid human (ph)VEGF-A(165) versus placebo	patients with chronic myocardial ischemia	double blind
NCT00090714 *ongoing* [NCT00090714] n=NA follow-up:	recombinant plasmid DNA [pVGI.1(VEGF2)] gene therapy versus placebo	patients with severe Angina Pectoris	Parallel groups double blind

References

REVASC (Stewart), 2006:
AGENT 3 and 4 pooled, 0:
AGENT-1 (Grines), 2002:
AGENT-2 (Grines), 2003:
AGENT-3, 0:
AGENT-4, 0:
AWARE, 0:
EUROINJECT-ONE (Gyngysi), 2005:
NCT00090714, :

3 growth factor

Trial	Treatments	Patients	Trials design and methods
fibroblast growth factor vs placebo			

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Trial	Treatments	Patients	Trials design and methods
FIRST (Simons) , 2002 n=NA follow-up: 90 days	Single-bolus intracoronary administration of fibroblast growth factor-2 (FGF2) versus placebo	patients with coronary artery disease	double blind
GCSF Granulocyte-Colony Stimulating Factor vs placebo			
Seiler *ongoing* [NCT00886509] n=NA follow-up: 6 months	Subcutaneous Administration of Pegylated Granulocyte-Colony Stimulating Factor versus placebo	patients with stable coronary artery disease treatable by PCI	Parallel groups double blind
vascular endothelial growth factor vs placebo			
VIVA (Henry) , 2003 n=NA follow-up: 12 days	intracoronary and intravenous infusions of recombinant human vascular endothelial growth factor protein (rhVEGF) versus placebo	patients with stable exertional angina, unsuitable for standard revascularization	double blind
VEGF vs placebo			
EMAT *ongoing* [NCT00134433] n=NA follow-up:	growth factor (VEGF) angiogenesis along the diffusely diseased, non-directly bypassed LAD segment at a dose of 2 mg versus palcebo	patients undergoing surgical perivascular angiogenic therapy	Factorial plan double blind

References

FIRST (Simons), 2002:
Seiler, :
VIVA (Henry), 2003:
EMAT, :

4 stem cells

Trial	Treatments	Patients	Trials design and methods
autologous bone marrowderived mononuclear cells vs placebo			
Ramshorst , 2009 [ISRCTN58194927] n=25/25 follow-up: 6 months	intramyocardial injection of 100 x 10(6) autologous bone marrow-derived mononuclear cells versus placebo	patients with chronic myocardial ischemia	Parallel groups double blind Netherlands
CD34+ cells vs placebo			
Losordo , 2011 [NCT00300053] n=167 follow-up: 6 months	intramyocardial injection of autologous CD34+ cells versus placebo	patients with refractory angina who have exhausted all other treatment options	Parallel groups double-blind

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Trial	Treatments	Patients	Trials design and methods
mesenchymal stem cells vs placebo			
Kumar *ongoing* [NCT00883727] n=NA follow-up: 6 months	Intravenous ex Vivo Cultured Adult Allogenic Mesenchymal Stem Cells versus placebo	in patients with ST elevated acute myocardial infarction (STEMI)	Parallel groups double blind India
stem cells CD34+ vs placebo			
Losordo , 2007 [NCT00081913] n=NA follow-up:	Injection of Autologous CD34-Positive Cells versus placebo	Patientswith Canadian Cardiovascular Society class 3 or 4 angina who were undergoing optimal medical treatment and who were not candidates for mechanical revascularization	Parallel groups double blind

References

Ramshorst, 2009:
Losordo, 2011:
Kumar, :
Losordo, 2007:

5 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.

TrialResults-center is non-profit and self-funded.