Clinical trials of cell-based therapies for acute myocardial infarction in PCI

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1 growth factor

Trial	Treatments	Patients	Trials design and methods
G-CSF vs control			
Deng , 2006 n=10/10 follow-up: 12 months	granulocyte colony stimulating factor (G-CSF) versus control	-	China
FIRSTLINE-AMI (Ince) , 2005 n=25/25 follow-up: 4 months (1y)	granulocyte colony stimulating factor (G-CSF) versus usual care	patients with ST-elevation myocardial infarction undergoing primary PCI with stenting and abciximab	open germany
MAGIC (G-CSF) (Kang) , 2004 n=10/7 follow-up: 6 montsh	granulocyte colony stimulating factor (G-CSF) versus control	patients with myocardial infarction who underwent coronary stenting for the culprit lesion of infarction	open
MAGIC 1 (Kang) , 2007 n=NA follow-up: 24 months	granulocyte colony stimulating factor (G-CSF) versus control	patients with myocardial infarction	open
MAGIC Cell-3-DES (Kang) , 2006 n=27/29 follow-up: 6 months	peripheral blood stem cells mobilized by G-CSF for 3 days and delivered to infarcted myocardium via intracoronary infusion versus control	patients with recent or old myocardial infarction who underwent coronary revascularization with DES	open Korea
RIGENERA (Leone) , 2007 n=NA follow-up: 5 months	granulocyte colony stimulating factor (G-CSF) versus control	patients with large anterior wall AMI at high risk of unfavorable remodeling and with successful primary or rescue percutaneous coronary intervention and LVEF<50%	open
Suarez de Lezo (G-CSF) , 2007 n=10/10 follow-up: 3 months	systemic administration of granulocyte colony-stimulating factor (G-CSF) versus control	patients with revascularized anterior wall AMI and depressed left ventricular function (ejection fraction <45%)	open
Suzuki , 2006 n=NA follow-up: 6 months	granulocyte colony stimulating factor (G-CSF) versus control	patients with angina or AMI	open
Takano , 2007 n=18/22 follow-up: 6 months	granulocyte colony stimulating factor (G-CSF) versus control	patients with AMI related with the left anterior descending coronary artery, who underwent successful percutaneous coronary intervention	open Japan

continued...

Trial	Treatments	Patients	Trials design and methods
G-CSF vs placebo			
Ellis , 2006 [NCT00215124] n=18 follow-up: 1 months	granulocyte colony stimulating factor (G-CSF) at 5 escalating to 10 microg/kg per day subcutaneously for 5 days versus placebo	patients with large acute myocardial infarction	double blind
G-CSF-STEMI (Engelmann) , 2006 n=23/21 follow-up: 3 months	granulocyte colony stimulating factor (G-CSF) versus placebo	patients with late revascularized subacute STEMI	double blind germany
REVIVAL-2 (Zohlnhfer) , 2006 [NCT00126100] n=56/58 follow-up: 6 months	granulocyte colony stimulating factor (G-CSF) versus placebo	patients with acute myocardial infarction after successful mechanical reperfusion reduces infarct size	Parallel groups double blind Germany
STEMMI (Ripa) , 2006 n=39/39 follow-up: 6 months	granulocyte colony stimulating factor (G-CSF) versus placebo	patients with ST-elevation myocardial infarction	double blind
Valgimigli , 2005 n=10/10 follow-up: 6 months	granulocyte colony stimulating factor (G-CSF) versus placebo	patients with STEMI	double blind Italy

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2 myoblasts

Trial	Treatments	Patients	Trials design and methods
percutaneous skeletal-myoblast cell therapy vs placebo			

continued...

Trial	Treatments	Patients	Trials design and methods
MARVEL *ongoing* n=14/6 follow-up: 6 mo	autologous myoblasts by intramyocardial injection at doses containing 400 or 800 million cells versus sham procedure	patients with post-MI myocardial scarring	Parallel groups double blind

References

MARVEL, :

3 stem cells

Trial	Treatments	Patients	Trials design and methods
autologous bone marrow stem cells vs control			
ASTAMi (Lunde) , 2006 n=50/50 follow-up: 6 months	intracoronary injection of autologous mononuclear BMC (stem cells 0.68 10^8) *versus* *control*(*Heparanizedplasma*)	patients with acute ST-elevation myocardial infarction of the anterior wall treated with percutaneous coronary intervention	parallel group open
BOOSt (Meyer) , 2004 n=30/30 follow-up: 6 months	stem cells mean 2.46 10^9 *versus* *control*(*Heparanisedplasma*)	successful percutaneous coronary intervention (PCI) for acute ST-segment elevation myocardial infarction	parallel group open
Chen , 2004 n=NA follow-up: 6 months	-	-	
Huang , 2006 n=20/20 follow-up: 6 months	intracoronary transplantation of autologous BM-MNC via a micro-catheter right after PCI (stem cells mean 1.8 10^8) *versus* *placebo*(*Heparanisedsaline*)	patients with first onset of acute inferior-wall myocardial infarction aged <or = 75, treated with emergent percutaneous coronary intervention	parallel group open
Karpov , 2005 n=10/10 follow-up: 6 months	intracoronary injection of bone marrow mononuclear cells (stem cells mean 88.5 10^6) *versus* *control*	patients with acute myocardial infarction.	parallel group NA
Li , 2007 n=35/23 follow-up: 6 months	autologous peripheral blood stem cell transplantation by intracoronary infusion (stem cells mean 7.25 10^7) *versus* *control*	patients with AMI	parallel group open
MAGIC (cell infusion) , 2004 n=10/7 follow-up:	intracoronary infusion of collected peripheral blood stem-cells versus control	patients with myocardial infarction who underwent coronary stenting for the culprit lesion of infarction	

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Trial	Treatments	Patients	Trials design and methods
MAGIC Cell-3-DES (Kang) , 2006 n=25/25 follow-up: 6 months	intracoronary infusion of mobilized peripheral blood stem cells by granulocyte colony-stimulating factor (stem cells 1-2 10^9) *versus* *control*	patients with myocardial infarction who underwent coronary revascularization with DES for the culprit lesion	parallel group open
Meluzin HD , 2006 n=22/22 follow-up: 3 months	intracoronar mononuclear bone marrow cells (stem cells 10^8) *versus* *control*(*Cellsuspensionmedia*)	patients with a first acute myocardial infarction	parallel group open
Meluzin LD , 2006 n=22/22 follow-up: 3 months	intracoronar mononuclear bone marrow cells (stem cells 10^7) *versus* *control*(*Cellsuspensionmedia*)	patients with a first acute myocardial infarction	parallel group open
Penicka , 2007 n=14/10 follow-up: 4 months	Intracoronary injection of autologous bone marrow-derived mononuclear cells (stem cells 26.4 10^8) *versus* *control*	patients with large anterior acute myocardial infarction	parallel group open
Ruan , 2005 n=9/11 follow-up: 6 months	intracoronary injection of bone-marrow cell (stem cells dose NA) versus control (Diluted serum)	with acute myocardial infarction and anterior descending coronary artery occlusion proven by angiography	parallel group open
Suarez de Lezo (cell) , 2007 n=10/10 follow-up: 3 months	intracoronary infusion of autologous mononuclear bone marrow cells (9 10^8) *versus* *control*(*Salinecontaining*0.1%*heparin*)	patients with revascularized anterior wall AMI and depressed left ventricular function (ejection fraction <45%)	parallel group open
TCT-STAMI (Ge) , 2006 n=10/10 follow-up: 6 months	emergent intracoronary autologous bone marrow cell transplantation (4 $10^7 SC$) *versus* *control*	patients admitted within 24 h after the onset of a first AMI	parallel group NA
cardiosphere-derived stem cells vs control			
CADUCEUS *ongoing* [NCT00893360] n=NA follow-up: 12 months	Autologous cardiosphere-derived stem cell intra-coronary infusion versus control	patients with ischemic left ventricular dysfunction and a recent myocardial infarction	Parallel groups open
autologous bone marrow stem cells vs placebo			
Janssens , 2006 n=33/34 follow-up: 4 months	stem cells mean 1.7 10^8 *versus* *placebo*(*Salineand*5%*autologousserum*)	patienst with successful percutaneous coronary intervention for STEMI	parallel group double blind
REPAIR-AMI (Schachinger) , 2006 [NCT00279175] n=95/92 follow-up: 4 months	intracoronary infusion of progenitor cells derived from bone marrow (stem cells mean 2.36 10^8) *versus* *placebo*($X-$ *vivomediaand*20%*autologousserum*)	patients with acute myocardial infarction	double blind

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Trial	Treatments	Patients	Trials design and methods
TIME *ongoing* n=NA follow-up:	autologous bone marrow-derived mononuclear cells (BMMNCs) versus placebo	patients with moderate-to-large anterior AMIs who have undergone successful percutaneous coronary intervention of the left anterior descending coronary artery and have a left ventricular (LV) ejection fraction </=45% by echocardiography.	Parallel groups double blind
Autologous Skeletal Myoblasts vs placebo			
NCT00975234 *ongoing* [NCT00975234] n=NA follow-up:	Intra-lesion injection of autologous skeletal myoblasts versus placebo	Patients With Old Myocardial Infarction	
E-CMM vs placebo			
ENACT-AMI *ongoing* n=NA follow-up:	autologous E-CMMs (culture modified circulating mononuclear cells), or E-CMMs transfected with human endothelial nitric oxide synthase delivered by coronary injection into the infarct-related artery versus placebo	-	

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