

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

TrialResults-center www.trialresultscenter.org

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 monthsh	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 (Zohlhfer) , 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

2

References

Deng, 2006:

Deng Z, Yang C, Deng H, Yang A, Geng T, Chen X, Ma A, Liu Z Effects of GM-CSF on the stem cells mobilization and plasma C-reactive protein levels in patients with acute myocardial infarction. *Int J Cardiol* 2006;113:92-6 [[16891014](#)] [10.1016/j.ijcard.2006.06.014](#)

FIRSTLINE-AMI (Ince), 2005:

Ince H, Petzsch M, Kleine HD, Eckard H, Rehders T, Burska D, Kische S, Freund M, Nienaber CA Prevention of left ventricular remodeling with granulocyte colony-stimulating factor after acute myocardial infarction: final 1-year results of the Front-Integrated Revascularization and Stem Cell Liberation in Evolving Acute Myocardial Infarction by Granulocyte Colony-Stimulating Factor (FIRSTLINE-AMI) Trial. *Circulation* 2005;112:173-80 [[16159869](#)]

MAGIC (G-CSF) (Kang), 2004:

Kang HJ, Kim HS, Zhang SY, Park KW, Cho HJ, Koo BK, Kim YJ, Soo Lee D, Sohn DW, Han KS, Oh BH, Lee MM, Park YB Effects of intracoronary infusion of peripheral blood stem-cells mobilised with granulocyte-colony stimulating factor on left ventricular systolic function and restenosis after coronary stenting in myocardial infarction: the MAGIC cell randomised clinical trial. *Lancet* 2004;363:751-6 [[15016484](#)]

MAGIC 1 (Kang), 2007:

Kang HJ, Kim HS, Koo BK, Kim YJ, Lee D, Sohn DW, Oh BH, Park YB Intracoronary infusion of the mobilized peripheral blood stem cell by G-CSF is better than mobilization alone by G-CSF for improvement of cardiac function and remodeling: 2-year follow-up results of the Myocardial Regeneration and Angiogenesis in Myocardial Infarction with G-CSF and Intra-Coronary Stem Cell Infusion (MAGIC Cell) 1 trial. *Am Heart J* 2007;153:237.e1-8 [[17239682](#)]

MAGIC Cell-3-DES (Kang), 2006:

Kang HJ, Lee HY, Na SH, Chang SA, Park KW, Kim HK, Kim SY, Chang HJ, Lee W, Kang WJ, Koo BK, Kim YJ, Lee DS, Sohn DW, Han KS, Oh BH, Park YB, Kim HS Differential effect of intracoronary infusion of mobilized peripheral blood stem cells by granulocyte colony-stimulating factor on left ventricular function and remodeling in patients with

acute myocardial infarction versus old myocardial infarction: the MAGIC Cell-3-DES randomized, controlled trial. *Circulation* 2006;114:I145-51 [16820564]

RIGENERA (Leone), 2007:

Leone AM, Galiuto L, Garramone B, Rutella S, Giannico MB, Brugaletta S, Perfetti M, Liuzzo G, Porto I, Burzotta F, Niccoli G, Biasucci LM, Leone G, Rebuzzi AG, Crea F Usefulness of granulocyte colony-stimulating factor in patients with a large anterior wall acute myocardial infarction to prevent left ventricular remodeling (the rigenera study). *Am J Cardiol* 2007;100:397-403 [17659916] [10.1016/j.amjcard.2007.03.036](#)

Suarez de Lezo (G-CSF), 2007:

Suarez de Lezo J, Herrera C, Pan M, Romero M, Pavlovic D, Segura J, Snchez J, Ojeda S, Torres A [Regenerative therapy in patients with a revascularized acute anterior myocardial infarction and depressed ventricular function] *Rev Esp Cardiol* 2007;60:357-65 [17521544]

Suzuki, 2006:

Suzuki K, Nagashima K, Arai M, Uno Y, Misao Y, Takemura G, Nishigaki K, Minatoguchi S, Watanabe S, Tei C, Fujiwara H Effect of granulocyte colony-stimulating factor treatment at a low dose but for a long duration in patients with coronary heart disease. *Circ J* 2006;70:430-7 [16565560]

Takano, 2007:

Takano H, Hasegawa H, Kuwabara Y, Nakayama T, Matsuno K, Miyazaki Y, Yamamoto M, Fujimoto Y, Okada H, Okubo S, Fujita M, Shindo S, Kobayashi Y, Komiyama N, Takekoshi N, Imai K, Himi T, Ishibashi I, Komuro I Feasibility and safety of granulocyte colony-stimulating factor treatment in patients with acute myocardial infarction. *Int J Cardiol* 2007;122:41-7 [17182126] [10.1016/j.ijcard.2006.11.016](#)

Ellis, 2006:

Ellis SG, Penn MS, Bolwell B, Garcia M, Chacko M, Wang T, Brezina KJ, McConnell G, Topol EJ Granulocyte colony stimulating factor in patients with large acute myocardial infarction: results of a pilot dose-escalation randomized trial. *Am Heart J* 2006;152:1051.e9-14 [17161051] [10.1016/j.ahj.2006.09.003](#)

Ellis SG, Penn MS, Bolwell B, Garcia M, Chacko M, Wang T, Brezina KJ, McConnell G, Topol EJ Granulocyte colony stimulating factor in patients with large acute myocardial infarction: results of a pilot dose-escalation randomized trial. *Am Heart J* 2006;152:1051.e9-14 [17161051] [10.1016/j.ahj.2006.09.003](#)

G-CSF-STEMI (Engelmann), 2006:

Engelmann MG, Theiss HD, Hennig-Theiss C, Huber A, Wintersperger BJ, Werle-Ruedinger AE, Schoenberg SO, Steinbeck G, Franz WM Autologous bone marrow stem cell mobilization induced by granulocyte colony-stimulating factor after subacute ST-segment elevation myocardial infarction undergoing late revascularization: final results from the G-CSF-STEMI (Granulocyte Colony-Stimulating Factor ST-Segment Elevation Myocardial Infarction) trial. *J Am Coll Cardiol* 2006;48:1712-21 [17045910]

REVIVAL-2 (Zohlhfer), 2006:

Zohlhfer D, Ott I, Mehilli J, Schmig K, Michalk F, Ibrahim T, Meisetschlger G, von Wedel J, Bollwein H, Seyfarth M, Dirschinger J, Schmitt C, Schwaiger M, Kastrati A, Schmig A Stem cell mobilization by granulocyte colony-stimulating factor in patients with acute myocardial infarction: a randomized controlled trial. *JAMA* 2006;295:1003-10 [16507801]

STEMMI (Ripa), 2006:

Ripa RS, Jrgensen E, Wang Y, Thune JJ, Nilsson JC, Sndergaard L, Johnsen HE, Kber L, Grande P, Kastrup J Stem cell mobilization induced by subcutaneous granulocyte-colony stimulating factor to improve cardiac regeneration after acute ST-elevation myocardial infarction: result of the double-blind, randomized, placebo-controlled stem cells in myocardial infarction (STEMMI) trial. *Circulation* 2006;113:1983-92 [16531621]

Valgimigli, 2005:

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 <i>ongoing</i> 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 $0.68 \cdot 10^8$) <i>versus</i> <i>control(Heparanizedplasma)</i>	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 $2.46 \cdot 10^9$ <i>versus</i> <i>control(Heparanisedplasma)</i>	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 $1.8 \cdot 10^8$) <i>versus</i> <i>placebo(Heparanisedsaline)</i>	patients with first onset of acute inferior-wall myocardial infarction aged ≤ 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 $88.5 \cdot 10^6$) <i>versus</i> <i>control</i>	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 $7.25 \cdot 10^7$) <i>versus</i> <i>control</i>	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	

continued...

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 $1-2 \cdot 10^9$) <i>versus</i> <i>control</i>	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) <i>versus</i> <i>control(Cellsuspensionmedia)</i>	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) <i>versus</i> <i>control(Cellsuspensionmedia)</i>	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 $26.4 \cdot 10^8$) <i>versus</i> <i>control</i>	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) <i>versus</i> <i>control (Diluted serum)</i>	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 ($9 \cdot 10^8$) <i>versus</i> <i>control(Salinecontaining0.1%heparin)</i>	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 ($4 \cdot 10^7 SC$) <i>versus</i> <i>control</i>	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 <i>versus</i> <i>control</i>	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 $1.7 \cdot 10^8$ <i>versus</i> <i>placebo(Salineand5%autologousserum)</i>	patientst 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 $2.36 \cdot 10^8$) <i>versus</i> <i>placebo(X – vivomediaand20%autologousserum)</i>	patients with acute myocardial infarction	double blind

continued...

Trial	Treatments	Patients	Trials design and methods
TIME <i>ongoing</i> 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 $\leq 45\%$ by echocardiography.	Parallel groups double blind
Autologous Skeletal Myoblasts vs placebo			
NCT00975234 <i>ongoing</i> [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 <i>ongoing</i> 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	-	

References

ASTAMi (Lunde), 2006:
 BOOST (Meyer), 2004:
 Chen, 2004:
 Huang, 2006:
 Karpov, 2005:
 Li, 2007:
 MAGIC (cell infusion), 2004:
 MAGIC Cell-3-DES (Kang), 2006:
 Meluzin HD, 2006:
 Meluzin LD, 2006:
 Penicka, 2007:
 Ruan, 2005:
 Suarez de Lezo (cell), 2007:
 TCT-STAMI (Ge), 2006:
 CADUCEUS, :
 Janssens, 2006:
 REPAIR-AMI (Schachinger), 2006:
 TIME, :
 NCT00975234, :
 ENACT-AMI, :

4 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.