

# Clinical trials of G-CSF

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## 1 acute myocardial infarction

Trial	Treatments	Patients	Trials design and methods
<b>G-CSF vs control</b>			
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

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
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
<b>G-CSF vs placebo</b>			
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

More details and results :

- cell-based therapies for acute myocardial infarction in PCI at <http://www.trialresultscenter.org/go-Q313>

## 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;114:1145-51 [[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](https://doi.org/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, Sanchez 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](https://doi.org/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](https://doi.org/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](https://doi.org/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 (Zohnhfer ), 2006:**

Zohnhfer 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:**

Valgimigli M, Rigolin GM, Cittanti C, Malagutti P, Curello S, Percoco G, Bugli AM, Della Porta M, Bragotti LZ, Ansani L, Mauro E, Lanfranchi A, Giganti M, Feggi L, Castoldi G, Ferrari R *Eur Heart J* 2005;26:1838-45 [[15860518](#)] [10.1093/eurheartj/ehi289](#)