

# Clinical trials of increasing hemoglobin concentration for heart failure in all type of patients

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## 1 erythropoietin

Trial	Treatments	Patients	Trials design and methods
<b>beta-erythropoietin vs placebo</b>			
Palazzuoli , 2006 n=20/20 follow-up:	s.c. beta-EPO for 3 months twice weekly and oral iron versus placebo + oral iron	patients with anemia and resistant CHF	double blind
<b>darbepoetin alfa vs placebo</b>			
Ponikowski , 2007 [NCT00117234] n=19/22 follow-up: 27 weeks	Subcutaneous (SC) Darbepoetin Alfa versus subcutaneous placebo	patients with Symptomatic Congestive Heart Failure (CHF) and Anemia	Parallel groups double blind
Parissis , 2008 n=21/11 follow-up:	3-month darbepoetin alpha regimen at 1.5 microg/kg every 20 days plus oral iron versus placebo plus oral iron	CHF patients NYHA II-III, LV ejection fraction [EF] <40% , hemoglobin level <12.5 g/dL, serum creatinine level <2.5 mg/dL	
Parissis , 2009 n=30 follow-up:	3-month darbepoetin alfa regimen at 1.5 microg/kg every 20 days plus oral iron versus placebo plus oral iron	patients with CHF (LV ejection fraction [LVEF] <40% , hemoglobin <12.5 g/dl, and serum creatinine <2.5 mg/dl	
Kourea , 2008 n=21/20 follow-up:	3-month darbepoietin-alpha at 1.5 microg/Kg every 20 days plus iron orally versus placebo plus iron orally	CHF patients NYHA II-III; left ventricular ejection fraction <40% ; hemoglobin<12.5 g/dl; serum creatinine<2.5 mg/dl	double blind
STAMINA-HeFT (Ghali) , 2008 [NCT00049985] n=162/157 follow-up: 27 weeks	darbepoetin alfa SC every 2 weeks for 1 year (target hemoglobin, 14.0+/-1.0 g/dL). versus placebo	Patients with symptomatic HF, left ventricular ejection fraction <or = 40% , and hemoglobin >or = 9.0 g/dL and <or = 12.5 g/dL	Parallel groups double blind
van Veldhuisen , 2007 [NCT00086086] n=110/55 follow-up: 27 weeks	darbepoetin alfa subcutaneously every 2 weeks for 26 weeks at a starting weight-adjusted dose of 0.75 mcg/kg or a fixed dose of 50 mcg versus placebo	Patients with chronic heart failure (>=3 months), left ventricular ejection fraction <= 40% , and Hb 9.0 to 12.5 g/dL	Parallel groups double blind

## References

Palazzuoli, 2006:

Palazzuoli A, Silverberg D, Iovine F, Capobianco S, Giannotti G, Calabr A, Campagna SM, Nuti R Erythropoietin improves anemia exercise tolerance and renal function and reduces B-type natriuretic peptide and hospitalization in patients with heart failure and anemia. *Am Heart J* 2006;152:1096.e9-15 [[17161060](#)]

**Ponikowski, 2007:**

Ponikowski P, Anker SD, Szachniewicz J, Okonko D, Ledwidge M, Zymliński R, Ryan E, Wasserman SM, Baker N, Rosser D, Rosen SD, Poole-Wilson PA, Banasiak W, Coats AJ, McDonald K Effect of darbepoetin alfa on exercise tolerance in anemic patients with symptomatic chronic heart failure: a randomized, double-blind, placebo-controlled trial. *J Am Coll Cardiol* 2007;49:753-62 [[17306703](#)]

**Parissis, 2008:**

Parissis JT, Kourea K, Panou F, Farmakis D, Paraskevaïdis I, Ikonomidis I, Filippatos G, Kremastinos DT Effects of darbepoetin alpha on right and left ventricular systolic and diastolic function in anemic patients with chronic heart failure secondary to ischemic or idiopathic dilated cardiomyopathy. *Am Heart J* 2008;155:751.e1-7 [[18371487](#)]

**Parissis, 2009:**

Parissis JT, Kourea K, Andreadou I, Ikonomidis I, Markantonis S, Ioannidis K, Paraskevaïdis I, Iliodromitis E, Filippatos G, Kremastinos DT Effects of Darbepoetin Alfa on plasma mediators of oxidative and nitrosative stress in anemic patients with chronic heart failure secondary to ischemic or idiopathic dilated cardiomyopathy. *Am J Cardiol* 2009;103:1134-8 [[19361602](#)]

**Kourea, 2008:**

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**STAMINA-HeFT (Ghali), 2008:**

Ghali JK, Anand IS, Abraham WT, Fonarow GC, Greenberg B, Krum H, Massie BM, Wasserman SM, Trotman ML, Sun Y, Knusel B, Armstrong P Randomized double-blind trial of darbepoetin alfa in patients with symptomatic heart failure and anemia. *Circulation* 2008;117:526-35 [[18195176](#)]

**van Veldhuisen, 2007:**

van Veldhuisen DJ, Dickstein K, Cohen-Solal A, Lok DJ, Wasserman SM, Baker N, Rosser D, Cleland JG, Ponikowski P Randomized, double-blind, placebo-controlled study to evaluate the effect of two dosing regimens of darbepoetin alfa in patients with heart failure and anaemia. *Eur Heart J* 2007;28:2208-16 [[17681958](#)]

## 2 intravenous iron

Trial	Treatments	Patients	Trials design and methods
<b>ferric carboxymaltose vs placebo</b>			
<b>FAIR-HF (Anker) , 2009</b> n=304/155 follow-up: 24 weeks	ferric carboxymaltose versus placebo	patients with systolic heart failure and iron deficiency	Parallel groups double blind 11 countries

## References

**FAIR-HF (Anker), 2009:**

Anker SD, Comin Colet J, Filippatos G, Willenheimer R, Dickstein K, Drexler H, Lscher TF, Bart B, Banasiak W, Niegowska J, Kirwan BA, Mori C, von Eisenhart Rothe B, Pocock SJ, Poole-Wilson PA, Ponikowski P Ferric Carboxymaltose in Patients with Heart Failure and Iron Deficiency. *N Engl J Med* 2009 Nov 17;: [[19920054](#)] [10.1056/NEJMoa0908355](#)

### 3 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.