

# Clinical trials of Carvedilol

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## 1 acute myocardial infarction

Trial	Treatments	Patients	Trials design and methods
<b>Carvedilol vs placebo</b>			
<a href="#">Basu , 1997</a> n=77/74 follow-up: 6 months	Carvedilol target dose 25 mg BID versus placebo	Patients with acute MI <24h	Parallel groups Double blind UK

More details and results :

- beta-blockers for acute myocardial infarction in long term beta-blockers at <http://www.trialresultscenter.org/go-Q42>

## References

### Basu , 1997:

Basu S, Senior R, Raval U, van der Does R, Bruckner T, Lahiri A Beneficial effects of intravenous and oral carvedilol treatment in acute myocardial infarction. A placebo-controlled, randomized trial Circulation 1997;96:183-91 [[9236433](#)]

## 2 hypertension

Trial	Treatments	Patients	Trials design and methods
<b>carvedilol vs placebo</b>			
<a href="#">Cice et al , 2003</a> n=58/56 follow-up: 12 months	65279;Carvedilol 50 mg/day versus matched placebo	dialysis patients with dilated cardiomyopathy	
<a href="#">Nakao et al , 2007</a> n=57/51	Carvedilol 20 mg/day versus matched placebo	-	

More details and results :

- anti hypertensive agents for hypertension in patients undergoing dialysis at <http://www.trialresultscenter.org/go-Q281>

## References

### Cice et al, 2003:

Cice G, Ferrara L, D'Andrea A, D'Isa S, Di Benedetto A, Cittadini A, Russo PE, Golino P, Calabr R J Am Coll Cardiol 2003;41:1438-44 [12742278]

### Nakao et al, 2007:

Nakao N, Hasegawa H, Fujimori A, Seno H, Toriyama T, J Am Soc Nephrol 2007;18 (suppl): 709A [0]

## 3 heart failure

Trial	Treatments	Patients	Trials design and methods
<b>carvedilol vs placebo</b>			
ANZ-HeFT , 1997 n=207/208 follow-up: 19 mo (range 18-24 mo)	carvedilol target dose 25mg twice daily versus placebo	chronic stable heart failure, NYHA 1-3	Parallel groups Double blind Australia & New Zealand
Parker , 1996 n=696/398 follow-up: 6.5 mo (1 day - 15.1 mo)	carvedilol target dose 25 mg twice daily versus placebo	patients with heart failure and ejection fraction <0.35	Parallel groups Double blind US
Carvedilol U.S. Trials (elderly subgroup) , 1996 n=554	Carvedilol versus placebo	Patients aged 65 years and older	
COPERNICUS (elderly subgroup) , 2001 n=1102	Carvedilol versus placebo	Patients aged 59 years and older	
Metra , 1994 n=20/20 follow-up: 4 mo	carvedilol versus placebo	NYHA 2-3, IDC	
Olsen , 1995 n=36/23 follow-up: 4 mo	carvedilol versus placebo	NYHA 2-4, IDC/CAD	
Krum , 1995 n=33/16 follow-up: 3.5 mo	carvedilol 25 mg twice daily during 14 weeks versus placebo	Patients with advanced heart failure (NYHA 3-4), EF ≤0.35	
Bristow (MOCHA) , 1996 n=261/84 follow-up: 6.5-8 mo	carvedilol versus placebo	NYHA 2-4, IDC/CAD	Parallel groups Double blind

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>Colucci , 1996</b> n=232/134 follow-up: 213 days (0.6 years)	carvedilol versus placebo	mild symptomatic heart failure; ejection fraction ≤0.35; 6-minute walk test of 450-550m; on optimal standard therapy including ACE inhibitors	Parallel groups Double blind US
<b>Cohn , 1997</b> n=70/35 follow-up: <8 mo	carvedilol versus placebo	NYHA 3-4, IDC/CAD	
<b>CAPRICORN , 2001</b> n=975/984 follow-up: 1.3 years	carvedilol target dose 25mg twice daily versus placebo	proven acute myocardial infarction and a left-ventricular ejection fraction of <=40%	Parallel groups Double blind 17 countries
<b>COPERNICUS , 2002</b> n=1156/1133 follow-up: 10.4 months	carvedilol target dose of 25 mg twice daily versus placebo	patients with symptoms of heart failure at rest or on minimal exertion and with an ejection fraction <25% (but not volume-overloaded)	Parallel groups Double blind worldwide (21 countries)
<b>carvedilol vs enalapril</b>			
<b>CARMEN (carvedilol alone) , 2004</b> n=191/190 follow-up: 18 months	carvedilol (target 25 mg bid) versus enalapril (target 10 mg bid)	patients with mild heart failure	ND
<b>carvedilol vs metoprolol</b>			
<b>COMET , 2003</b> n=1511/1518 follow-up: 4.83 years	carvedilol (target dose 25 mg twice daily) versus metoprolol tartrate target dose 50 mg twice daily	chronic heart failure (NYHA IIIIV) with a previous admission for a cardiovascular reason and ejection fraction of less than 0.35, and have been treated optimally with diuretics and angiotensin converting enzyme inhibitors unless not tolerated.	Parallel groups Double blind 15 European countries
<b>carvedilol+enalapril vs enalapril</b>			
<b>CARMEN (carvedilol+enalapril) , 2004 ongoing</b> n=191/190 follow-up: 18 months	carvedilol (target 25 mg bid) + enalapril (target 10 mg bid) versus enalapril (target 10 mg bid)	patients with mild heart failure	NA

More details and results :

- beta-blockers for heart failure in all type of heart failure at <http://www.trialresultscenter.org/go-Q44>
- beta-blockers for heart failure in elderly patients at <http://www.trialresultscenter.org/go-Q119>

## References

### **ANZ-HeFT, 1997:**

Randomised, placebo-controlled trial of carvedilol in patients with congestive heart failure due to ischaemic heart disease. Australia/New Zealand Heart Failure Research Collaborative Group. *Lancet* 1997;349:375-80 [9033462]

, Effects of carvedilol, a vasodilator-beta-blocker, in patients with congestive heart failure due to ischemic heart disease. Australia-New Zealand Heart Failure Research Collaborative Group. *Circulation* 1995; 92:212-8 [7600653]

, Randomised, placebo-controlled trial of carvedilol in patients with congestive heart failure due to ischaemic heart disease. Australia/New Zealand Heart Failure Research Collaborative Group. *Lancet* 1997; 349:375-80 [9033462]

### **Parker, 1996:**

Packer M, Colucci WS, Sackner-Bernstein JD, Liang CS, Goldscher DA, Freeman I, Kukin ML, Kinhal V, Udelson JE, Klapholz M, Gottlieb SS, Pearle D, Cody RJ, Gregory JJ, Kantrowitz NE, LeJemtel TH, Young ST, Lukas MA, Shusterman NH, Double-blind, placebo-controlled study of the effects of carvedilol in patients with moderate to severe heart failure. The PRECISE Trial. Prospective Randomized Evaluation of Carvedilol on Symptoms and Exercise. *Circulation* 1996; 94:2793-9 [8941104]

Packer M, Bristow MR, Cohn JN, Colucci WS, Fowler MB, Gilbert EM, Shusterman NH, The effect of carvedilol on morbidity and mortality in patients with chronic heart failure. U.S. Carvedilol Heart Failure Study Group. *N Engl J Med* 1996; 334:1349-55 [8614419]

### **Carvedilol U.S. Trials (elderly subgroup), 1996:**

Packer M, Bristow MR, Cohn JN, Colucci WS, Fowler MB, Gilbert EM, Shusterman NH The effect of carvedilol on morbidity and mortality in patients with chronic heart failure. U.S. Carvedilol Heart Failure Study Group. *N Engl J Med* 1996;334:1349-55 [8614419]

### **COPERNICUS (elderly subgroup), 2001:**

Best PJ, Lennon R, Ting HH, Bell MR, Rihal CS, Holmes DR, Berger PB The impact of renal insufficiency on clinical outcomes in patients undergoing percutaneous coronary interventions. *J Am Coll Cardiol* 2002;39:1113-9 [11923033]

### **Metra, 1994:**

Metra M, Nardi M, Giubbini R, Dei Cas L, Effects of short- and long-term carvedilol administration on rest and exercise hemodynamic variables, exercise capacity and clinical conditions in patients with idiopathic dilated cardiomyopathy. *J Am Coll Cardiol* 1994; 24:1678-87 [7963115]

### **Olsen, 1995:**

Olsen SL, Gilbert EM, Renlund DG, Taylor DO, Yanowitz FD, Bristow MR, Carvedilol improves left ventricular function and symptoms in chronic heart failure: a double-blind randomized study. *J Am Coll Cardiol* 1995; 25:1225-31 [7722114]

### **Krum, 1995:**

Krum H, Sackner-Bernstein JD, Goldsmith RL, Kukin ML, Schwartz B, Penn J, Medina N, Yushak M, Horn E, Katz SD, et al, Double-blind, placebo-controlled study of the long-term efficacy of carvedilol in patients with severe chronic heart failure. *Circulation* 1995; 92:1499-506 [7664433]

### **Bristow (MOCHA), 1996:**

Bristow MR, Gilbert EM, Abraham WT, Adams KF, Fowler MB, Hershberger RE, Kubo SH, Narahara KA, Ingersoll H, Krueger S, Young S, Shusterman N, Carvedilol produces dose-related improvements in left ventricular function and survival in subjects with chronic heart failure. MOCHA Investigators. *Circulation* 1996; 94:2807-16 [8941106]

### **Colucci, 1996:**

Colucci WS, Packer M, Bristow MR, Gilbert EM, Cohn JN, Fowler MB, Krueger SK, Hershberger R, Uretsky BF, Bowers JA, Sackner-Bernstein JD, Young ST, Holcslaw TL, Lukas MA, Carvedilol inhibits clinical progression in patients with mild symptoms of heart failure. US Carvedilol Heart Failure Study Group. *Circulation* 1996; 94:2800-6 [8941105]

**Cohn, 1997:**

Cohn JN, Fowler MB, Bristow MR, Colucci WS, Gilbert EM, Kinhal V, Krueger SK, Lejemtel T, Narahara KA, Packer M, Young ST, Holcslaw TL, Lukas MA, Safety and efficacy of carvedilol in severe heart failure. The U.S. Carvedilol Heart Failure Study Group. *J Card Fail* 1997; 3:173-9 [9330125]

Cohn JN, Fowler MB, Bristow MR, Colucci WS, Gilbert EM, Kinhal V, Krueger SK, Lejemtel T, Narahara KA, Packer M, Young ST, Holcslaw TL, Lukas MA Safety and efficacy of carvedilol in severe heart failure. The U.S. Carvedilol Heart Failure Study Group. *J Card Fail* 1997 Sep;3:173-9 [9330125]

**CAPRICORN, 2001:**

Dargie HJ Effect of carvedilol on outcome after myocardial infarction in patients with left-ventricular dysfunction: the CAPRICORN randomised trial. *Lancet* 2001 May 5;357:1385-90 [11356434]

**COPERNICUS, 2002:**

Packer M, Fowler MB, Roecker EB, Coats AJ, Katus HA, Krum H, Mohacsi P, Rouleau JL, Tendera M, Staiger C, Holcslaw TL, Amann-Zalan I, DeMets DL Effect of carvedilol on the morbidity of patients with severe chronic heart failure: results of the carvedilol prospective randomized cumulative survival (COPERNICUS) study. *Circulation* 2002 Oct 22;106:2194-9 [12390947]

Packer M, Coats AJ, Fowler MB, Katus HA, Krum H, Mohacsi P, Rouleau JL, Tendera M, Castaigne A, Roecker EB, Schultz MK, DeMets DL Effect of carvedilol on survival in severe chronic heart failure. *N Engl J Med* 2001 May 31;344:1651-8 [11386263]

**CARMEN (carvedilol alone), 2004:**

Remme WJ, Riegger G, Hildebrandt P, Komajda M, Jaarsma W, Bobbio M, Soler-Soler J, Scherhag A, Lutiger B, Ryden L The benefits of early combination treatment of carvedilol and an ACE-inhibitor in mild heart failure and left ventricular systolic dysfunction. The carvedilol and ACE-inhibitor remodelling mild heart failure evaluation trial (CARMEN). *Cardiovasc Drugs Ther* 2004 Jan;18:57-66 [15115904]

Komajda M, Lutiger B, Madeira H, Thygesen K, Bobbio M, Hildebrandt P, Jaarsma W, Riegger G, Ryden L, Scherhag A, Soler-Soler J, Remme WJ Tolerability of carvedilol and ACE-Inhibition in mild heart failure. Results of CARMEN (Carvedilol ACE-Inhibitor Remodelling Mild CHF Evaluation). *Eur J Heart Fail* 2004 Jun;6:467-75 [15182773]

Komajda M, Lutiger B, Madeira H, Thygesen K, Bobbio M, Hildebrandt P, Jaarsma W, Riegger G, Rydn L, Scherhag A, Soler-Soler J, Remme WJ Tolerability of carvedilol and ACE-Inhibition in mild heart failure. Results of CARMEN (Carvedilol ACE-Inhibitor Remodelling Mild CHF Evaluation). *Eur J Heart Fail* 2004 Jun;6:467-75 [15182773]

**COMET, 2003:**

Poole-Wilson PA, Swedberg K, Cleland JG, Di Lenarda A, Hanrath P, Komajda M, Lubsen J, Lutiger B, Metra M, Remme WJ, Torp-Pedersen C, Scherhag A, Skene A Comparison of carvedilol and metoprolol on clinical outcomes in patients with chronic heart failure in the Carvedilol Or Metoprolol European Trial (COMET): randomised controlled trial. *Lancet* 2003 Jul 5;362:7-13 [12853193]

**CARMEN (carvedilol+enalapril), 2004:**

ongoing trial

Remme WJ, Riegger G, Hildebrandt P, Komajda M, Jaarsma W, Bobbio M, Soler-Soler J, Scherhag A, Lutiger B, Rydn L The benefits of early combination treatment of carvedilol and an ACE-inhibitor in mild heart failure and left ventricular systolic dysfunction. The carvedilol and ACE-inhibitor remodelling mild heart failure evaluation trial (CARMEN). *Cardiovasc Drugs Ther* 2004 Jan;18:57-66 [15115904]

Komajda M, Lutiger B, Madeira H, Thygesen K, Bobbio M, Hildebrandt P, Jaarsma W, Riegger G, Rydn L, Scherhag A, Soler-Soler J, Remme WJ Tolerability of carvedilol and ACE-Inhibition in mild heart failure. Results of CARMEN (Carvedilol ACE-Inhibitor Remodelling Mild CHF Evaluation). Eur J Heart Fail 2004 Jun;6:467-75 [15182773]

Remme WJ The Carvedilol and ACE-Inhibitor Remodelling Mild Heart Failure Evaluation trial (CARMEN)—rationale and design. Cardiovasc Drugs Ther 2001 Jan;15:69-77 [11504166]

## 4 diabetes type 2

Trial	Treatments	Patients	Trials design and methods
<b>carvedilol vs metoprolol</b>			
GEMINI , 2004 n=498/737 follow-up: 5 months	6.25- to 25-mg dose of carvedilol twice daily versus 50- to 200-mg dose of metoprolol tartrate twice daily	patients with hypertension and type 2 diabetes mellitus receiving renin-angiotensin system blockade	Parallel groups double-blind

More details and results :

- anti hypertensive agents for diabetes type 2 in patients with or without hypertension at <http://www.trialresultscenter.org/go-Q414>

## References

### GEMINI, 2004:

Bakris GL, Fonseca V, Katholi RE, McGill JB, Messerli FH, Phillips RA, Raskin P, Wright JT Jr, Oakes R, Lukas MA, Anderson KM, Bell DS Metabolic effects of carvedilol vs metoprolol in patients with type 2 diabetes mellitus and hypertension: a randomized controlled trial. JAMA 2004;292:2227-36 [15536109] [10.1001/jama.292.18.2227](https://doi.org/10.1001/jama.292.18.2227)

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