

Clinical trials of calcium channel blockers for heart failure in all type of patients

TrialResults-center www.trialresultscenter.org

1 calcium-channel blockers

Trial	Treatments	Patients	Trials design and methods
amlodipine vs control			
Packer , 1991 <i>unpublished</i> n=NA follow-up: 2 months	-	CHD multiple cause, NYHA class II-III	Double blind
Smith , 1994 n=NA follow-up: 3 months	-	CHD multiple cause, NYHA class II-III	Double blind
Binkley , 1996 <i>unpublished</i> n=NA follow-up: 3 months	-	CHD multiple cause, NYHA class II-III	Double blind
Udelson , 1996 <i>unpublished</i> n=NA follow-up: 3 months	-	patients with congestive heart failure due to ischaemic heart disease, NYHA class II-III	Double blind
Ghali , 1997 <i>unpublished</i> n=NA follow-up: 3 months	-	CHD multiple cause, NYHA class III-IV	Double blind
nicardipine vs control			
Gheorghide , 1991 <i>unpublished</i> n=NA follow-up: 4 months	-	CHD multiple cause, NYHA class III	Double blind
Abrams , 1993 <i>unpublished</i> n=NA follow-up: 4 months	-	CHD multiple cause, NYHA class III-IV	Double blind
vs placebo			
De Vries , 1996 n=25 follow-up: 2 months	lacidipine 4 mg once daily versus placebo	patients with symptoms of mild to moderate heart failure, despite treatment with diuretics, digoxin, and angiotensin converting enzyme inhibitors	double blind the Netherlands
amlodipine vs placebo			
PRAISE , 1996 n=571/582 follow-up: median 13.8 mo (range 6-33 mo)	amlodipine 10 mg once daily versus placebo	patients with severe chronic heart failure and ejection fractions of less than 30 percent appl	Parallel groups Double blind US
PRAISE II , 2000 <i>unpublished</i> n=826/826 follow-up: up to 4 years	Amlodipine versus placebo	heart failure in non ischemic cardiomyopathy	

continued...

Trial	Treatments	Patients	Trials design and methods
Diltiazem vs placebo			
DiDi , 1996 n=92/94 follow-up: 24 months	diltiazem 60mg three times daily versus placebo	idiopathic dilated cardiomyopathy and LVEF<0.50	Parallel groups Double blind germany
Liao , 1998 n=114/107 follow-up: 6 months	diltiazem 30mg twice daily versus control (vitamin B1 30mg twice daily)	patients with dilated cardiomyopathy	Parallel groups Simple aveugle China
felodipine vs placebo			
VHeFT III , 1997 n=224/226 follow-up: mean 18mo (range 3-39 mo)	felodipine 5mg twice daily versus placebo	male patient over 18 years with heart failure	Parallel groups Double blind US
Kassis , 1987 n=18/18 follow-up: 3 weeks	felodipine 10 mg twice daily versus placebo	patients on conventional therapy for severe CHF	Cross over Double blind Denmark
Kassis , 1990 n=10/10 follow-up: 6 months	felodipine 10 mg BID versus placebo	severe congestive heart failure (NYHA class III)	Parallel groups Double blind Denmark
2 Littler , 1995 n=132/119 follow-up: 3 months	felodipine extended release 2.5-10mg twice daily (in addition to existing background medication) for 12 weeks versus placebo	patients with NYHA class II-III stable congestive heart failure despite treatment with ACE inhibitors, diuretic and digoxin or any combinaison of these drugs	Parallel groups Double blind UK
isradipine vs placebo			
Van den Toreen , 1996 n=19 follow-up: 3 months	isradipine up to 5mg 3 times daily versus placebo	patients with congestive heart failure due to ischaemic heart disease, NYHA class II-III, FE<40%	Parallel groups Double blind The NetherlanA
mibefradil vs placebo			
MACH 1 , 2000 n=1295/1295 follow-up: 1.6 years	mibefradil titrated up to100mg daily versus placebo	Patients with moderate to severe congestive heart failure (NYHA class II to IV and left ventricular fraction ,35%).pj	Parallel groups Double aveugle US, Canada, Europe and Israel
Nisoldipine vs placebo			
Rousseau , 1994 n=16/16 follow-up: 2 months	nisoldipine 20 mg once daily versus placebo	patients with congestive heart failure due to ischaemic heart disease, NYHA class II	Double blind
Gaudron , 1996 <i>unpublished</i> n=NA follow-up: 18 months	Nisoldipine versus placebo	patients with congestive heart failure due to ischaemic heart disease, NYHA class II, FE<=45%	
nisoldipine vs captopril			

continued...

Trial	Treatments	Patients	Trials design and methods
Schofer , 1990 n=24 follow-up: 3 months	nisoldipine (2 X 10 mg) versus captopril (3 X 25 mg)	patients with congestive heart failure due to ischaemic heart disease, NYHA class II-III	Double blind
felodipine vs enalapril			
Dunselman , 1990 n=9/11 follow-up: 4 months	felodipine 10 mg b.i.d. versus enalapril 10 mg b.i.d.	patients with congestive heart failure due to ischaemic heart disease and NYHA class III	Double blind
De Vries , 1995 n=22/24 follow-up: 4 months	felodipine 2.5mg twice daily versus enalapril 2.5mg twice daily	patients NYHA class II-III with left ventricular ejection fraction <0.4, symptoms of CHD despite therapy with diuretics and digoxin	Parallel groups Double blind the Netherlands

References

Packer, 1991:

Packer M, Nicod P, Khanderia RE Randomized, multicenter, double-blind, placebo-controlled evaluation of amlodipine in patients with mild-to-moderate heart failure (abstr). J Am Coll Cardiol 1991;17:274A.

Smith, 1994:

Udelson JE, DeAbate CA, Berk M, Neuberger G, Packer M, Vijay NK, Gorwitt J, Smith WB, Kukin ML, LeJemtel T, Levine TB, Konstam MA Effects of amlodipine on exercise tolerance, quality of life, and left ventricular function in patients with heart failure from left ventricular systolic dysfunction. Am Heart J 2000 Mar;139:503-10 [10689266]

Binkley, 1996:

Binkley PF, Nunziata E, Hatton PS, Cody RJ. Dose and circadian dependent autonomic response to vasodilation with amlodipine in congestive heart failure (abstr) J Am Coll Cardiol 1996;27:774.

Udelson, 1996:

Udelson JE, DeAbate CA, Vijay N. Effect of amlodipine on exercise tolerance and quality of life in mild to moderate heart failure with systolic dysfunction (abstr). J Am Coll Cardiol 1996;27:774.

Ghali, 1997:

Ghali JK, Pressler M, Nye R, Cropp A. Is suppression of the neurohormonal system a prerequisite to improve survival in patients with heart failure and impaired left ventricular systolic function (abstr). Circulation 1997;95:385.

Gheorghiade, 1991:

Georghiade M, Hall V, Goldberg Ad, Levine TB, Goldstein S.q Long term clinical and neurohumoral effects of nicardipine in patients with severe heart failure on maintenance therapy with angiotensin converting enzyme inhibitors (abstr). J Am Coll Cardiol 1991;17:274A.

Abrams, 1993:

Abrams J, Bristow MR, Chiang Y. Double-blind evaluation of the safety and efficacy of nicardipine in patients with advanced chronic heart failure (abstr). J Am Coll Cardiol 1993;21:377A.

De Vries, 1996:

de Vries RJ, Dunselman PH, Chin Kon Sung UG, van Veldhuisen DJ, Corbeij HM, van Gilst WH, Lie KI Effects of lacidipine on peak oxygen consumption, neurohormones and invasive haemodynamics in patients with mild to moderate chronic heart failure. Heart 1996;75:159-64 [8673754]

PRAISE, 1996:

Packer M, O'Connor CM, Ghali JK, Pressler ML, Carson PE, Belkin RN, Miller AB, Neuberger GW, Frid D, Wertheimer JH, Cropp AB, DeMets DL Effect of amlodipine on morbidity and mortality in severe chronic heart failure. Prospective Randomized Amlodipine Survival Evaluation Study Group. N Engl J Med 1996 Oct 10;335:1107-14 [8813041]

PRAISE II , 2000:

Cabell CH, Trichon BH, Velazquez EJ, Dumesnil JG, Anstrom KJ, Ryan T, Miller AB, Belkin RN, Cropp AB, O'Connor CM, Jollis JG Importance of echocardiography in patients with severe nonischemic heart failure: the second Prospective Randomized Amlodipine Survival Evaluation (PRAISE-2) echocardiographic study. *Am Heart J* 2004;147:151-7 [[14691434](#)]

DiDi, 1996:

Figulla HR, Gietzen F, Zeymer U, Raiber M, Hegselmann J, Soballa R, Hilgers R Diltiazem improves cardiac function and exercise capacity in patients with idiopathic dilated cardiomyopathy. Results of the Diltiazem in Dilated Cardiomyopathy Trial. *Circulation* 1996 Aug 1;94:346-52 [[8759075](#)]

Liao , 1998:

Liao YH Interventional study of diltiazem in dilated cardiomyopathy: a report of multiple centre clinical trial in China. Chinese Cooperative Group of Diltiazem Intervention Trial in Dilated Cardiomyopathy. *Int J Cardiol* 1998 Mar 13;64:25-30 [[9579813](#)]

VHeFT III, 1997:

Cohn JN, Ziesche S, Smith R, Anand I, Dunkman WB, Loeb H, Cintron G, Boden W, Baruch L, Rochin P, Loss L Effect of the calcium antagonist felodipine as supplementary vasodilator therapy in patients with chronic heart failure treated with enalapril: V-HeFT III. Vasodilator-Heart Failure Trial (V-HeFT) Study Group. *Circulation* 1997;96:856-63 [[9264493](#)]

Kassis, 1987:

Kassis E, Amtorp O Cardiovascular and neurohumoral postural responses and baroreceptor abnormalities during a course of adjunctive vasodilator therapy with felodipine for congestive heart failure. *Circulation* 1987 Jun;75:1204-13 [[2882868](#)]

Kassis E, Amtorp O, Waldorff S, Fritz-Hansen P Efficacy of felodipine in chronic congestive heart failure: a placebo controlled haemodynamic study at rest and during exercise and orthostatic stress. *Br Heart J* 1987 Nov;58:505-11 [[3314956](#)]

Kassis, 1990:

Kassis E, Amtorp O Short- and long-term controlled studies of felodipine in patients with congestive heart failure. *J Cardiovasc Pharmacol* 1990;15 Suppl 4:S26 [[1693721](#)]

Kassis E, Amtorp O Long-term clinical, hemodynamic, angiographic, and neurohumoral responses to vasodilation with felodipine in patients with chronic congestive heart failure. *J Cardiovasc Pharmacol* 1990 Mar;15:347-52 [[1691355](#)]

Littler, 1995:

Littler WA, Sheridan DJ Placebo controlled trial of felodipine in patients with mild to moderate heart failure. UK Study Group. *Br Heart J* 1995 May;73:428-33 [[7786657](#)]

Van den Toreen, 1996:

van den Toreen EW, van Veldhuisen DJ, van Bruggen A, van den Broek SA, van Gilst WH, Lie KI Acute hemodynamic and long-term clinical effects of isradipine in patients with coronary artery disease and chronic heart failure. A double-blind, placebo-controlled study. *Int J Cardiol* 1996 Jan;53:37-43 [[8776276](#)]

MACH 1, 2000:

Levine TB, Bernink PJ, Caspi A, Elkayam U, Geltman EM, Greenberg B, McKenna WJ, Ghali JK, Giles TD, Marmor A, Reisin LH, Ammon S, Lindberg E Effect of mibefradil, a T-type calcium channel blocker, on morbidity and mortality in moderate to severe congestive heart failure: the MACH-1 study. Mortality Assessment in Congestive Heart Failure Trial. *Circulation* 2000 Feb 22;101:758-64 [[10683349](#)]

Rousseau, 1994:

Rousseau MF, Melin J, Benedict CR, Ahn S, Raphael D, Bornemann M, Pouleur H Effects of nisoldipine therapy on myocardial perfusion and neuro-hormonal status in patients with severe ischaemic left ventricular dysfunction. *Eur Heart J* 1994 Jul;15:957-64 [[7925518](#)]

Gaudron, 1996:

Gaudron P, Kugler I, Hu K, Ellis C, Ertl G Long-term calcium-channel blockade causes left ventricular dilation in asymptomatic patients with chronic infarction (abstr). *J Am Coll Cardiol* 1996;27:774.BJ

Schofer, 1990:

Schofer J, Hobuss M, Aschenberg W, Tews A Acute and long-term haemodynamic and neurohumoral response to nisoldipine vs captopril in patients with heart failure: a randomized double-blind study. *Eur Heart J* 1990 Aug;11:712-21 [[1975780](#)]

Dunselman, 1990:

Dunselman PH, van der Mark TW, Kuntze CE, van Bruggen A, Hamer JP, Scaf AH, Wesseling H, Lie KI Different results in cardiopulmonary exercise tests after long-term treatment with felodipine and enalapril in patients with congestive heart failure due to ischaemic heart disease. Eur Heart J 1990 Mar;11:200-6 [2318222]

De Vries, 1995:

de Vries RJ, Quere M, Lok DJ, Sijbring P, Bux JJ, van Veldhuisen DJ, Dunselman PH Comparison of effects on peak oxygen consumption, quality of life, and neurohormones of felodipine and enalapril in patients with congestive heart failure. Am J Cardiol 1995 Dec 15;76:1253-8 [7503006]

2 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.