

# Clinical trials of vasodilators therapy for heart failure in all type of patient

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## 1 epoprostenol

Trial	Treatments	Patients	Trials design and methods
<b>epoprostenol vs standard care</b>			
<b>FIRST , 1997</b> n=237/234 follow-up: 3 and 6 months	epoprostenol infusion versus standard care	Patients with class IIIB/IV congestive heart failure and decreased left ventricular ejection fraction	Parallel groups NA

## References

### FIRST, 1997:

Califf RM, Adams KF, McKenna WJ, Gheorghide M, Uretsky BF, McNulty SE, Darius H, Schulman K, Zannad F, Handberg-Thurmond E, Harrell FE Jr, Wheeler W, Soler-Soler J, Swedberg K A randomized controlled trial of epoprostenol therapy for severe congestive heart failure: The Flolan International Randomized Survival Trial (FIRST). Am Heart J 1997;134:44-54 [[9266782](#)]

## 2 human B-type natriuretic peptide

Trial	Treatments	Patients	Trials design and methods
<b>nesiritide vs placebo</b>			
<b>FUSION 2 , 2008</b> [NCT00091520] n=911 follow-up: 12 weeks	nesiritide (2 g/kg bolus plus 0.01 g/kg-per-minute infusion for four to six hours) versus placebo	patients with ACC/AHA stage C/D heart failure with two recent heart-failure hospitalizations, an ejection fraction of less than 40% , and NYHA class 4 symptoms or NYHA class 3 symptoms with creatinine clearance less than 60 mL/min	Parallel groups double-blind
<b>nesiritide vs standard care</b>			
<b>FUSION 1 , 2004</b> [NCT00270361] n=NA follow-up: 12 weeks	nesiritide 0.005 microg/kg/min or 0.010 microg/kg/min once weekly versus standard care	outpatient with co-morbid advanced heart failure and renal insufficiency	Parallel groups open

## References

### FUSION 2, 2008:

Yancy CW, Krum H, Massie BM, Silver MA, Stevenson LW, Cheng M, Kim SS, Evans R The Second Follow-up Serial Infusions of Nesiritide (FUSION II) trial for advanced heart failure: study rationale and design. Am Heart J 2007;153:478-84 [[17383282](#)]

Yancy CW, Krum H, Massie BM, Silver MA, Stevenson LW, Cheng M, Kim SS, Evans R Safety and efficacy of outpatient nesiritide in patients with advanced heart failure: results of the Second Follow-Up Serial Infusions of Nesiritide (FUSION II) trial. *Circ Heart Fail* 2008;1:9-16 [19808265] [10.1161/CIRCHEARTFAILURE.108.767483](https://doi.org/10.1161/CIRCHEARTFAILURE.108.767483)

#### **FUSION 1, 2004:**

Yancy CW, Singh A Potential applications of outpatient nesiritide infusions in patients with advanced heart failure and concomitant renal insufficiency (from the Follow-Up Serial Infusions of Nesiritide [FUSION I] trial). *Am J Cardiol* 2006 Jul 15;98:226-9 [16828598]

Yancy CW, Saltzberg MT, Berkowitz RL, Bertolet B, Vijayaraghavan K, Burnham K, Oren RM, Walker K, Horton DP, Silver MA Safety and feasibility of using serial infusions of nesiritide for heart failure in an outpatient setting (from the FUSION I trial). *Am J Cardiol* 2004 Sep 1;94:595-601 [15342289]

Yancy CW, Singh A Potential applications of outpatient nesiritide infusions in patients with advanced heart failure and concomitant renal insufficiency (from the Follow-Up Serial Infusions of Nesiritide [FUSION I] trial). *Am J Cardiol* 2006 Jul 15;98:226-9 [16828598]

### 3 hydralazine

Trial	Treatments	Patients	Trials design and methods
<b>hydralazine vs control</b>			
Chatterjee , 1980 n=NA follow-up:	oral hydralazine versus NA	patients with chronic CHF	
<b>hydralazine vs placebo</b>			
Franciosa , 1982 n=16/16 follow-up: 20 weeks	hydralazine 200 mg daily versus placebo	patients with class III and IV symptoms while they were taking digitalis and diuretics	double blind
Conradson , 1984 n=NA follow-up: 1 year	hydralazine versus placebo	patients with chronic congestive heart failure (NYHA class III)	
Magorien , 1984 n=NA follow-up:	hydralazine 100 mg orally every eight hours versus placebo	patients with idiopathic dilated cardiomyopathy	double blind

### References

#### **Chatterjee, 1980:**

Chatterjee K, Rouleau JL, Massie BM Hydralazine in chronic CHF. *Acta Med Scand Suppl* 1981;652:99-113 [6949469]

#### **Franciosa, 1982:**

Franciosa JA, Weber KT, Levine TB, Kinasewitz GT, Janicki JS, West J, Henis MM, Cohn JN Hydralazine in the long-term treatment of chronic heart failure: lack of difference from placebo. *Am Heart J* 1982 Sep;104:587-94 [7051796]

#### **Conradson , 1984:**

Conradson TB, Rydn L, Ahlmark G, Saetre H, Persson S, Nyquist O, Wernersson B Clinical efficacy of hydralazine in chronic heart failure: one-year double-blind placebo-controlled study. *Am Heart J* 1984;108:1001-6 [6385678]

#### **Magorien , 1984:**

Magorien RD, Unverferth DV, Leier CV Hydralazine therapy in chronic congestive heart failure. Sustained central and regional hemodynamic responses. *Am J Med* 1984;77:267-74 [6431812]

## 4 hydralazine-ISDN

Trial	Treatments	Patients	Trials design and methods
<b>vs placebo</b>			
<b>Ghose (vs placebo) , 1993</b> n=50/51 follow-up: 6 months	hydralazine 100mg/d ISDN 60mg/d versus placebo	patientst with chronic congestive heart failure (NYHA III or IV) receiving conventional treatment with digoxin and diuretics	Parallel groups double blind
<b>hydralazine-ISDN vs placebo</b>			
<b>VHeFT I (hydralazine ISDN) , 1986</b> n=186/273 follow-up: 2.3 y (range 0.5-5.7 years)	hydralazine 300mg/d ISDN 160mg/d versus placebo	patientst with chronic congestive heart failure and cardiac dilatation (CT ratio>0.55) or LVEF <45% in association with reduced exercise tolerance	Parallel groups double blind
<b>vs captopril</b>			
<b>Ghose (vs captopril) , 1993</b> n=50/52 follow-up:	hydralazine ISDN , hydralazine 100mg/d ISDN 60mg/d versus	patientst with chronic congestive heart failure (NYHA III or IV) receiving conventional treatment with digoxin and diuretics	
<b>vs enalapril</b>			
<b>V-HeFT II , 1991</b> n=401/403 follow-up: 2.5y (range 0.5-5.7y)	hydralazine 300mg ISDN 160mg daily versus enalapril 20mg daily	men with chronic congestive heart failure and cardiac dilatation (CT ratio>0.55) or LVEF <45% in association with reduced exercise tolerance	Parallel groups double blind

## References

### Ghose (vs placebo), 1993:

Ghose JC, Chakraborty S, Mondal M, Bhandari B Effect of vasodilator therapy on mortality in chronic congestive heart failure. J Assoc Physicians India 1993 May;41:269-71 [8300456]

### VHeFT I (hydralazine ISDN), 1986:

Cohn JN, Archibald DG, Ziesche S, Franciosa JA, Harston WE, Tristani FE, Dunkman WB, Jacobs W, Francis GS, Flohr KH Effect of vasodilator therapy on mortality in chronic congestive heart failure. Results of a Veterans Administration Cooperative Study. N Engl J Med 1986;314:1547-52 [3520315] 10.1056/NEJM198606123142404

### Ghose (vs captopril) , 1993:

Ghose JC, Chakraborty S, Mondal M, Bhandari B Effect of vasodilator therapy on mortality in chronic congestive heart failure. J Assoc Physicians India 1993 May;41:269-71 [8300456]

### V-HeFT II, 1991:

Cohn JN, Johnson G, Ziesche S, Cobb F, Francis G, Tristani F, Smith R, Dunkman WB, Loeb H, Wong M A comparison of enalapril with hydralazine-isosorbide dinitrate in the treatment of chronic congestive heart failure. N Engl J Med 1991;325:303-10 [2057035]

Loeb HS, Johnson G, Henrick A, Smith R, Wilson J, Cremo R, Cohn JN Effect of enalapril, hydralazine plus isosorbide dinitrate, and prazosin on hospitalization in patients with chronic congestive heart failure. The V-HeFT VA Cooperative Studies Group. Circulation 1993;87:VI78-87 [8500244]

## 5 isosorbide dinitrate

Trial	Treatments	Patients	Trials design and methods
<b>isosorbide dinitrate vs placebo</b>			
<b>NICE (Lewis) , 1999</b> n=NA follow-up: 12 weeks	isosorbide-5-mononitrate 50 mg once daily versus placebo	patients (NYHA Class 2-3) treated for heart failure, all receiving captopril and most also furosemide	
<b>Franciosa , 1978</b> n=16/16 follow-up:	isosorbide dinitrate versus placebo	-	double blind

## References

### NICE (Lewis), 1999:

Lewis BS, Rabinowitz B, Schlesinger Z, Caspi A, Markiewicz W, Rosenfeld T, Sclarovsky S, Ermer W Effect of isosorbide-5-mononitrate on exercise performance and clinical status in patients with congestive heart failure. Results of the Nitrates in Congestive Heart Failure (NICE) Study. *Cardiology* 1999;91:1-7 [[10393392](#)]

### Franciosa , 1978:

Franciosa JA, Nordstrom LA, Cohn JN Nitrate therapy for congestive heart failure. *JAMA* 1978;240:443-6 [[351232](#)]

## 6 prazosin

Trial	Treatments	Patients	Trials design and methods
<b>prazosin vs placebo</b>			
<b>VHeFT I (prazosin) , 1986</b> n=183/273 follow-up: 2.3 y (range 0.5-5.7 years)	hydralazine 300mg/d ISDN 160mg/d , prazosin 2.5mg four times daily versus placebo	men with chronic congestive heart failure and cardiac dilatation (CT ratio>0.55) or LVEF <45% in association with reduced exercise tolerance	double blind
<b>Colucci , 1980</b> n=NA follow-up:	prazosin versus placebo	-	
<b>Markham , 1983</b> n=23 follow-up: 6 months	-	patients with congestive heart failure receiving a stable dose of digitalis and diuretics	double blind
<b>Higginbotham , 1983</b> n=NA follow-up:	prazosin versus placebo	-	

## References

### VHeFT I (prazosin), 1986:

Cohn JN, Archibald DG, Ziesche S, Franciosa JA, Harston WE, Tristani FE, Dunkman WB, Jacobs W, Francis GS, Flohr KH Effect of vasodilator therapy on mortality in chronic

congestive heart failure. Results of a Veterans Administration Cooperative Study. *N Engl J Med* 1986;314:1547-52 [[3520315](#)]

**Colucci, 1980:**

Colucci WS, Wynne J, Holman BL, Braunwald E Long-term therapy of heart failure with prazosin: a randomized double blind trial. *Am J Cardiol* 1980 Feb;45:337-44 [[6766650](#)]

**Markham, 1983:**

Markham RV Jr, Corbett JR, Gilmore A, Pettinger WA, Firth BG Efficacy of prazosin in the management of chronic congestive heart failure: a 6-month randomized, double-blind, placebo-controlled study. *Am J Cardiol* 1983 May 1;51:1346-52 [[6342353](#)]

**Higginbotham, 1983:**

Higginbotham MB, Morris KG, Bramlet DA, Coleman RE, Cobb FR Long-term ambulatory therapy with prazosin versus placebo for chronic heart failure: relation between clinical response and left ventricular function at rest and during exercise. *Am J Cardiol* 1983 Oct 1;52:782-8 [[6353898](#)]

## 7 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.

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