

Clinical trials of digoxin

TrialResults-center www.trialresultscenter.org

1 heart failure

Trial	Treatments	Patients	Trials design and methods
digoxin vs placebo			
Lee , 1982 n=25/25 follow-up: 53 days	65279;digoxin titrated to mean serum level of 1.15 ng/mL, mean dig dosage .435 mg/day versus placebo	outpatients without atrial fibrillation	cross-over double blind
Taggart , 1983 n=22/22 follow-up: 3 months	digoxin (mean plasma dig level 1.2 ng/mL) versus placebo (digoxin withdrawal)	patients with sinus rhythm who had a previous history of frank heart failure	cross-over double blind
Fleg , 1982 n=30/30 follow-up: 3 months	65279;digoxin titrated to serum level of 1.0 to 2.0 ng/mL versus placebo	patients with chronic clinically compensated congestive heart failure and normal sinus rhythm	cross-over dobl eblind
Captopril-Digoxin Multicenter Research Group (CDMRG) , 1988 n=NA follow-up: 6 months	65279;digoxin of .125-.375 mg/day titrated to serum levels of .7-2.5 ng/mL versus placebo (digoxin withdrawal)	patients with mild to moderate heart failure.	parallel group double blind
German and Austrian Xamoterol Study , 1988 n=NA follow-up: 3 months	65279;digoxin .125 mg twice daily (mean plasma dig level .87 ng/mL) versus placebo	patients aged 29-80 with mild to moderate heart failure	parallel group double blind
Guyatt , 1988 n=20/20 follow-up: 7 weeks	65279;digoxin titrated to serum level of 1.54 2.56 nmol/L (1.22.0 ng/mL), mean dig dosage 0.391 mg/day versus placebo	congestive heart failure patients in sinus rhythm	cross-over double blind
DiBianco , 1989 n=NA follow-up: 3 months	65279;digoxin .125-.5 mg/ day versus placebo	patients in sinus rhythm with moderately severe heart failure	parallel group double blind

continued...

Trial	Treatments	Patients	Trials design and methods
Pugh , 1989 n=44/44 follow-up: 2 months	65279;digoxin (patients usual dose) versus placebo (digoxin withdrawal)	patients with stable heart failure in sinus rhythm and plasma digoxin concentrations over 0.8 ng/ml	cross-over double blind
Blackwood , 1990 n=61 follow-up: 3 months	65279;digoxin .25 mg/day versus placebo	patients with heart failure	parallel group double blind
Radiance , 1993 n=85/93 follow-up: 3 months	digoxin titrated to serum level of 1.2 ng/mL (mean dig dosage .38 mg/day) versus placebo (digoxin withdrawal)	patients with New York Heart Association class II or III heart failure and left ventricular ejection fractions of 35 percent or less in normal sinus rhythm who were clinically stable while receiving digoxin, diuretics, and an angiotensin-converting-enzyme inhibitor (captopril or enalapril)	double blind
Proved , 1993 n=42/46 follow-up: 3 months	65279;digoxin titrated to serum level of 1.2 ng/mL (median dig dosage .375 mg/day) versus placebo (digoxin withdrawal)	patients with chronic, stable mild to moderate heart failure	withdrawal trial double blind
DIMT , 1993 n=55/53 follow-up: 6 months	65279;digoxin .25 mg/day (mean plasma level .94 ng/mL) versus placebo	patients with mild to moderate chronic heart failure	parallel group double blind
Digitalis Investigation Group (DIG) , 1997 [NCT00000476] n=3397/3403 follow-up: 37 mo (mean)	digoxin dosage at investigators discretion (median baseline dosage in main trial of .25 mg/day) versus placebo	patients with left ventricular ejection fractions of 0.45 or less and normal sinus rhythm	Parallel groups Double blind US, Canada

More details and results :

- digitalis glycosides for heart failure in all type of patient at <http://www.trialresultscenter.org/go-Q78>

References

Lee, 1982:

Lee DC, Johnson RA, Bingham JB, Leahy M, Dinsmore RE, Goroll AH, Newell JB, Strauss HW, Haber E Heart failure in outpatients: a randomized trial of digoxin versus placebo. N Engl J Med 1982 Mar 25;306:699-705 [7038483]

Taggart, 1983:

Taggart AJ, Johnston GD, McDevitt DG Digoxin withdrawal after cardiac failure in patients with sinus rhythm. J Cardiovasc Pharmacol 1983 Mar-Apr;5:229-34 [6188895]

Fleg, 1982:

Fleg JL, Gottlieb SH, Lakatta EG Is digoxin really important in treatment of compensated heart failure? A placebo-controlled crossover study in patients with sinus rhythm. *Am J Med* 1982 Aug;73:244-50 [7051826]

Captopril-Digoxin Multicenter Research Group (CDMRG), 1988:

Comparative effects of therapy with captopril and digoxin in patients with mild to moderate heart failure. The Captopril-Digoxin Multicenter Research Group. *JAMA* 1988 Jan 22-29;259:539-44 [2447297]

German and Austrian Xamoterol Study, 1988:

Double-blind placebo-controlled comparison of digoxin and xamoterol in chronic heart failure. The German and Austrian Xamoterol Study Group. *Lancet* 1988 Mar 5;1:489-93 [2893916]

Guyatt, 1988:

Guyatt GH, Sullivan MJ, Fallen EL, Tihal H, Rideout E, Halcrow S, Nogradi S, Townsend M, Taylor DW A controlled trial of digoxin in congestive heart failure. *Am J Cardiol* 1988 Feb 1;61:371-5 [3277366]

DiBianco, 1989:

DiBianco R, Shabetai R, Kostuk W, Moran J, Schlant RC, Wright R A comparison of oral milrinone, digoxin, and their combination in the treatment of patients with chronic heart failure. *N Engl J Med* 1989 Mar 16;320:677-83 [2646536]

Pugh, 1989:

Pugh SE, White NJ, Aronson JK, Grahame-Smith DG, Bloomfield JG Clinical, haemodynamic, and pharmacological effects of withdrawal and reintroduction of digoxin in patients with heart failure in sinus rhythm after long term treatment. *Br Heart J* 1989 Jun;61:529-39 [2503017]

Blackwood, 1990:

Blackwood R, Mayou RA, Garnham JC, Armstrong C, Bryant B Exercise capacity and quality of life in the treatment of heart failure. *Clin Pharmacol Ther* 1990 Sep;48:325-32 [2144803]

Radiance, 1993:

Packer M, Gheorghiade M, Young JB, Costantini PJ, Adams KF, Cody RJ, Smith LK, Van Voorhees L, Gourley LA, Jolly MK Withdrawal of digoxin from patients with chronic heart failure treated with angiotensin-converting-enzyme inhibitors. RADIANCE Study. *N Engl J Med* 1993 Jul 1;329:1-7 [8505940]

Proved, 1993:

Uretsky BF, Young JB, Shahidi FE, Yellen LG, Harrison MC, Jolly MK Randomized study assessing the effect of digoxin withdrawal in patients with mild to moderate chronic congestive heart failure: results of the PROVED trial. PROVED Investigative Group. *J Am Coll Cardiol* 1993 Oct;22:955-62 [8409069]

DIMT, 1993:

van Veldhuisen DJ, Man in 't Veld AJ, Dunselman PH, Lok DJ, Dohmen HJ, Poortermans JC, Withagen AJ, Pasteuning WH, Brouwer J, Lie KI Double-blind placebo-controlled study of ibopamine and digoxin in patients with mild to moderate heart failure: results of the Dutch Ibopamine Multicenter Trial (DIMT). *J Am Coll Cardiol* 1993 Nov 15;22:1564-73 [7901256]

Digitalis Investigation Group (DIG), 1997:

van Veldhuisen DJ, Man in 't Veld AJ, Dunselman PH, Lok DJ, Dohmen HJ, Poortermans JC, Withagen AJ, Pasteuning WH, Brouwer J, Lie KI Double-blind placebo-controlled study of ibopamine and digoxin in patients with mild to moderate heart failure: results of the Dutch Ibopamine Multicenter Trial (DIMT). *J Am Coll Cardiol* 1993 Nov 15;22:1564-73 [7901256]

The effect of digoxin on mortality and morbidity in patients with heart failure. The Digitalis Investigation Group. *N Engl J Med* 1997 Feb 20;336:525-33 [9036306]

Ahmed A, Waagstein F, Pitt B, White M, Zannad F, Young JB, Rahimtoola SH Effectiveness of digoxin in reducing one-year mortality in chronic heart failure in the Digitalis Investigation Group trial. Am J Cardiol 2009 Jan 1;103:82-7 [[19101235](#)]

Entry terms: Digoxin, Digacin, Digitek, Digoregen, Lanoxin, Lanoxin-PG, Lanoxin PG, Lenoxin, Digoxine Nativelle, Hemigoxine Nativelle, Dilanacin, Lanacordin, Lanicor, Lanoxicaps, Mapluxin, Digoxina Boehringer,