

# Clinical trials of digitalis glycosides for heart failure in all type of patient

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## 1 digoxin

| Trial  | Treatments  | Patients  | Trials design and methods      |
|--|---|---|--------------------------------|
| <b>digoxin vs placebo</b>  |   |   |                                |
| Lee , 1982<br>n=25/25<br>follow-up: 53 days  | 65279;digoxin titrated to mean serum level of 1.15 ng/mL, mean dig dosage .435 mg/day<br>versus<br>placebo                  | outpatients without atrial fibrillation   | cross-over<br>double blind     |
| Taggart , 1983<br>n=22/22<br>follow-up: 3 months   | digoxin (mean plasma dig level 1.2 ng/mL)<br>versus<br>placebo (digoxin withdrawal)   | patients with sinus rhythm who had a previous history of frank heart failure                        | cross-over<br>double blind     |
| Fleg , 1982<br>n=30/30<br>follow-up: 3 months  | 65279;digoxin titrated to serum level of 1.0 to 2.0 ng/mL<br>versus<br>placebo  | patients with chronic clinically compensated congestive heart failure and normal sinus rhythm       | cross-over<br>double blind     |
| Captopril-Digoxin Multicenter Research Group (CDMRG) , 1988<br>n=NA<br>follow-up: 6 months | 65279;digoxin of .125-.375 mg/day titrated to serum levels of .7-2.5 ng/mL<br>versus<br>placebo (digoxin withdrawal)        | patients with mild to moderate heart failure.   | parallel group<br>double blind |
| German and Austrian Xamoterol Study , 1988<br>n=NA<br>follow-up: 3 months                  | 65279;digoxin .125 mg twice daily (mean plasma dig level .87 ng/mL)<br>versus<br>placebo                                    | patients aged 29-80 with mild to moderate heart failure   | parallel group<br>double blind |
| Guyatt , 1988<br>n=20/20<br>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<br>versus<br>placebo | congestive heart failure patients in sinus rhythm   | cross-over<br>double blind     |
| DiBianco , 1989<br>n=NA<br>follow-up: 3 months   | 65279;digoxin .125-.5 mg/ day<br>versus<br>placebo  | patients in sinus rhythm with moderately severe heart failure                                       | parallel group<br>double blind |
| Pugh , 1989<br>n=44/44<br>follow-up: 2 months  | 65279;digoxin (patients usual dose )<br>versus<br>placebo (digoxin withdrawal)  | patients with stable heart failure in sinus rhythm and plasma digoxin concentrations over 0.8 ng/ml | cross-over<br>double blind     |
| Blackwood , 1990<br>n=61<br>follow-up: 3 months  | 65279;digoxin .25 mg/day<br>versus<br>placebo   | patients with heart failure   | parallel group<br>double blind |

continued...

| <b>Trial</b>   | <b>Treatments</b>  | <b>Patients</b>  | <b>Trials design and methods</b>              |
|--|--|--|---|
| <b>Radiance , 1993</b><br>n=85/93<br>follow-up: 3 months   | digoxin titrated to serum level of 1.2 ng/mL (mean dig dosage .38 mg/day)<br>versus<br>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                                  |
| <b>Proved , 1993</b><br>n=42/46<br>follow-up: 3 months   | 65279;digoxin titrated to serum level of 1.2 ng/mL (median dig dosage .375 mg/day)<br>versus<br>placebo (digoxin withdrawal) | patients with chronic, stable mild to moderate heart failure   | withdrawal trial<br>double blind              |
| <b>DIMT , 1993</b><br>n=55/53<br>follow-up: 6 months   | 65279;digoxin .25 mg/day (mean plasma level .94 ng/mL)<br>versus<br>placebo  | patients with mild to moderate chronic heart failure   | parallel group<br>double blind                |
| <b>Digitalis Investigation Group (DIG) , 1997</b><br>[NCT00000476]<br>n=3397/3403<br>follow-up: 37 mo (mean) | digoxin dosage at investigators discretion (median baseline dosage in main trial of .25 mg/day)<br>versus<br>placebo         | patients with left ventricular ejection fractions of 0.45 or less and normal sinus rhythm  | Parallel groups<br>Double blind<br>US, Canada |

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