Clinical trials of resynchronization (CRT) - defibrillators (ICD) for prevention of sudden death in primary prevention

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1 cardiac resynchronization therapy

Trial	Treatments	Patients	Trials design and methods
CRT vs no CRT			
MUSTIC-SR , 2001 n=58/58 follow-up: 3 months	CRT Medtronic/ELA medical versus CRT off	patients with severe heart failure (New York Heart Association class III) due to chronic left ventricular systolic dysfunction, with normal sinus rhythm and a duration of the QRS interval of more than 150 msec	Cross over Single blind
MIRACLE , 2002 n=228/225 follow-up: 6 months	CRT Medtronic versus CRT off	patients with moderate-to-severe symptoms of heart failure associated with an ejection fraction of 35 percent or less and a QRS interval of 130 msec	Parallel groups Bouble blind
PATH-CHF , 2002 n=NA follow-up: 1 month	CRT versus no CRT	patients with heart failure and ventricular conduction delay	Parallel groups open
MUSTIC AF , 2002 n=43/43 follow-up: 3 months	CRT Medtronic/ELA medical versus CRT off	patients with NYHA class III left ventricular systolic dysfunction, chronic atrial fibrillation, slow ventricular rate necessitating permanent ventricular pacing, and a wide QRS complex (paced width >or=200 ms)	Cross over Single blind
CARE-HF , 2005 n=409/404 follow-up: 29.4 months	CRT medtronic versus no CRT	patients with NYHA class III or IV heart failure due to left ventricular systolic dysfunction and cardiac dyssynchrony	parallel group open
RD-CHF , 2003 n=NA follow-up:	CRT versus no CRT	patients with advanced heart failure	Parallel groups
COMPANION (CRT vs MT) , 2004 n=617/308 follow-up: 16 months	CRT guidant versus no CRT, optimized medical therapy	patients with advanced heart failure (NYHA III or IV) due to ischemic and non-ischemic cardiomyopathy with EF <=35% and QRS duration >120 ms	Parallel groups open
Garrigue , 2002 n=NA follow-up:	CRT versus no CRT	patients with chronic atrial fibrillation, severe heart failure and QRS prolongation of >or = 140 ms	Parallel groups single blind

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2 Combined CRT + ICD

Trial	Treatments	Patients	Trials design and methods
Combined CRT + ICD vs no CRT no ICD			
AMIOVIRT , 2003 n=51/52 follow-up: 24 months	ICD versus amiodarone as medical therapy	patients with non ischemic cardiomyopathy with EF <=0.35 and Nonsustained ventricular tachycardia	Parallel groups open
COMPANION (CRT+ICD vs MT) , 2004 n=595/308 follow-up: 16 months	ICD+CRT versus no ICT no CRT, optimized medical therapy	patients with advanced heart failure (NYHA III or IV) due to ischemic and non-ischemic cardiomyopathy with EF <=0.35 and QRS duration >120 ms	Parallel groups open
Combined CRT + ICD vs CRT			

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Trial	Treatments	Patients	Trials design and methods
COMPANION (CRT+ICD vs CRT) , 2004 n=595/617 follow-up: 16 months	ICD+CRT versus CRT	patients with advanced heart failure (NYHA III or IV) due to ischemic and non-ischemic cardiomyopathy with EF <=0.35 and QRS duration >120 ms	Parallel groups open
Combined CRT + ICD vs ICD alone			
MIRACLE-ICD-II , 2004 n=85/101 follow-up: 6 months	ICD+CRT (and optimalmedical treatment) versus ICD (optimalmedical treatment)	NYHA class II heart failure patients on optimal medical therapy with a left ventricular (LV) ejection fraction <=35% , a QRS >=130 ms, and a class I indication for an ICD	Parallel groups double blind
MIRACLE-ICD-I , 2003 n=187/182 follow-up: 6 months	ICD+CRT (plus optimal medical treatment) versus ICD (plus optimal medical treatment)	patients with NYHA class III or IV congestive HF despite appropriate medical management	Parallel groups double blind
CONTAK-CD , 2003 n=245/245 follow-up: 4.7 months	ICD+CRT versus ICD (no CRT)	patients with symptomatic heart failure, intraventricular conduction delay, and malignant ventricular tachyarrhythmias	Parallel groups open

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3 Implantable cardioverter defibrillator therapy

Trial	Treatments	Patients	Trials design and methods
ICD vs no ICD			
MADIT , 1996 n=95/101 follow-up: 27 months	ICD versus anti arrhythmic drugs as conventional therapy	65279;patients with MI >=3 wk before entry and EF <=0.35 and 65279;Asymptomatic unsustained VT unrelated to an acute MI with inducible VT not suppressed after iv procainamide	Parallel groups open
MADIT-II , 2002 n=742/490 follow-up: 20 months	implantable cardiac defibrillator versus no ICD, optimized medical therapy	patients with a prior myocardial infarction and EF<=0.30	Parallel groups open
CAT , 2002 n=50/54 follow-up: 66 months	ICD versus no iCD, conventional therapy	patients with recent onset nonischemic cardiomyopathy withEF <=0.30	Parallel groups open
DEFINITE , 2004 n=229/229 follow-up: 29 months	ICD versus no ICD, standard medical therapy	patients with non ischemic cardiomyopathy with EF <0.36 and Nonsustained ventricular tachycardia or frequent premature ventricular complexes	Parallel groups open
SCD-HeFT (ICD vs placebo) , 2005 [NCT00000609] n=829/847 follow-up: 45.5 months	ICD versus optimized medical therapy	patients with ischemic and nonischemic cardiomyopathy withEF<=0.35	Parallel groups open
CABG-patch , 1997 [NCT00000540] n=446/454 follow-up: 32 months	ICD versus control	65279;patients undergoing CABG with EF <=0.35 and Abnormal signal-averaged electrocardiogram	Parallel groups open
DINAMIT , 2004 n=332/342 follow-up: 30 months	implantable cardioverter defibrillator versus no ICD, optimized medical therapy	patients within 640 days of myocardial infarct ischemic with EF<=0.35 and cardiac autonomic modulation (depressed heart rate variability or increased mean 24-hour heart rate)	Parallel groups open
MUSIT , 1999 n=351/353 follow-up: median 39 months	ICD or drugs as indicated by electrophysiologic testing versus no antiarrhythmic therapy	patients with ischemic cardiomyopathy with EF<=0.40 and 65279;Inducible, sustained ventricular tachyarrhythmias	Parallel groups open
SCD-HeFT (ICD vs amiodarone) , 2005 [NCT00000609] n=829/845 follow-up: 45.5 months	ICD versus optimized medical therapy with amiodarone	patients with ischemic and nonischemic cardiomyopathy withEF<=0.35	Parallel groups open

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Entry terms: catheter ablation

4 About TrialResults-center.org

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