

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 Double 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 ≥ 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 $\leq 35\%$ 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 ≥ 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 optimal medical treatment) versus ICD (optimal medical 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 \geq 3 wk before entry and EF \leq 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 \leq 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 with EF \leq 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 with EF \leq 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 \leq 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 \leq 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 \leq 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 with EF \leq 0.35	Parallel groups open

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Entry terms: catheter ablation

4 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.

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