

# 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
<b>CRT vs no CRT</b>			
<b>MUSTIC-SR , 2001</b> 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
<b>MIRACLE , 2002</b> 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
<b>PATH-CHF , 2002</b> n=NA follow-up: 1 month	CRT versus no CRT	patients with heart failure and ventricular conduction delay	Parallel groups open
<b>MUSTIC AF , 2002</b> 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 $\geq 200$ ms)	Cross over Single blind
<b>CARE-HF , 2005</b> 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
<b>RD-CHF , 2003</b> n=NA follow-up:	CRT versus no CRT	patients with advanced heart failure	Parallel groups
<b>COMPANION (CRT vs MT) , 2004</b> 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
<b>Garrigue , 2002</b> n=NA follow-up:	CRT versus no CRT	patients with chronic atrial fibrillation, severe heart failure and QRS prolongation of $\geq 140$ ms	Parallel groups single blind

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## 2 Combined CRT + ICD

Trial	Treatments	Patients	Trials design and methods
<b>Combined CRT + ICD vs no CRT no ICD</b>			
<b>AMIOVIRT , 2003</b> 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
<b>COMPANION (CRT+ICD vs MT) , 2004</b> 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
<b>Combined CRT + ICD vs CRT</b>			

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>COMPANION (CRT+ICD vs CRT) , 2004</b> 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
<b>Combined CRT + ICD vs ICD alone</b>			
<b>MIRACLE-ICD-II , 2004</b> 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
<b>MIRACLE-ICD-I , 2003</b> 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
<b>CONTAK-CD , 2003</b> 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
<b>ICD vs no ICD</b>			
<b>MADIT , 1996</b> 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
<b>MADIT-II , 2002</b> 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
<b>CAT , 2002</b> 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
<b>DEFINITE , 2004</b> 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
<b>SCD-HeFT (ICD vs placebo) , 2005</b> [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
<b>CABG-patch , 1997</b> [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
<b>DINAMIT , 2004</b> 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
<b>MUSIT , 1999</b> 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
<b>SCD-HeFT (ICD vs amiodarone) , 2005</b> [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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