

Clinical trials of CRT

TrialResults-center www.trialresultscenter.org

1 heart failure

| Trial | Treatments | Patients | Trials design and methods |
|---|--|---|---------------------------------|
| Combined CRT + ICD vs no CRT | | | |
| RethinQ , 2007 [NCT00132977] n=85/85 follow-up: 6 months | cardiac-resynchronization therapy ICD+CRT versus no cardiac-resynchronization therapy | patients with standard indication for an implantable cardioverter-defibrillator, NYHA 3, EF<35% , QRS<130ms, and evidence of mechanical dyssynchrony | Parallel groups open USA |
| CRT vs no CRT | | | |
| REVERSE , 2008 [NCT00271154].] n=419/191 follow-up: 12 months | CRT versus "placebo" | patients with NYHA functional class I or II heart failure with a QRS \geq 120 ms and a LV ejection fraction \leq 40% | Parallel groups double blind |
| 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 \geq 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 |

continued...

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|---|---|--|---|
| 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 |
| 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 | | | |
| 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 |
| MADIT CRT , 2009 [NCT00180271] n=1089/731 follow-up: 2 years | Cardiac resynchronization therapy with implantable cardioverter defibrillator versus implantable cardioverter defibrillator alone | patients with asymptomatic or mildly symptomatic heart failure (NYHA I/II), LEVF<=30% and QRS>=130ms | Parallel groups blinded United States, Europe |

continued...

| Trial | Treatments | Patients | Trials design and methods |
|---|--|---|--|
| RAFT , 2010 [NCT00251251] n=894/904 follow-up: 40 months | ICD plus CRT versus ICD alone | patients with New York Heart Association (NYHA) class II or III heart failure, a left ventricular ejection fraction of 30% or less, and an intrinsic QRS duration of 120 msec or more or a paced QRS duration of 200 msec or more | Parallel groups double-blind Canada, Europe, Turkey, Australia |
| 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 |
| CRT with triple site ventricular stimulation vs conventional cardiac resynchronization | | | |
| NCT00887237 <i>ongoing</i> n=NA follow-up: | CRT with triple site ventricular stimulation versus Conventional cardiac resynchronization | patients with NYHA Class III/IV heart failure | Parallel groups open |

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More details and results :

- resynchronization (CRT) - defibrillators (ICD) for heart failure in patients with non ischaemic cardiomyopathy at <http://www.trialresultscenter.org/go-Q15>
- resynchronization (CRT) - defibrillators (ICD) for heart failure in all type of patients at <http://www.trialresultscenter.org/go-Q104>
- resynchronization (CRT) - defibrillators (ICD) for heart failure in mildly symptomatic heart failure with prolonged QRS interval at <http://www.trialresultscenter.org/go-Q349>

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NCT00887237, :

ongoing trial

2 prevention of sudden death

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| 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 |
| CRT with triple site ventricular stimulation vs conventional cardiac resynchronization | | | |
| NCT00887237 ongoing n=NA follow-up: | CRT with triple site ventricular stimulation versus Conventional cardiac resynchronization | patients with NYHA Class III/IV heart failure | Parallel groups open |

More details and results :

- resynchronization (CRT) - defibrillators (ICD) for prevention of sudden death in primary prevention at <http://www.trialresultscenter.org/go-Q107>
- resynchronization (CRT) - defibrillators (ICD) for prevention of sudden death in heart failure at <http://www.trialresultscenter.org/go-Q109>

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