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 >=120 ms and a LV ejection fraction <=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 >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

continued...

Trial	Treatments	Patients	Trials design and methods
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

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

More details and results :

- resynchronization (CRT) - defibrillators (ICD) for heart failure in patients with non ichaemic 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 mildy 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

Trial	Treatments	Patients	Trials design and methods
Combined CRT + ICD vs no CRT			

continued...

Trial	Treatments	Patients	Trials design and methods
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			
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
Combined CRT + ICD vs no CRT no ICD			

continued...

Trial	Treatments	Patients	Trials design and methods
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
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 *ongoing* n=NA follow-up:	CRT with triple site ventricular stimulation versus Conventional cardiac resynchronization	patients with NYHA Class III/IV hert 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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