

Clinical trials of Combined CRT + ICD

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
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

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>

References

RethinQ, 2007:

Beshai JF, Grimm RA, Nagueh SF, Baker JH 2nd, Beau SL, Greenberg SM, Pires LA, Tchou PJ Cardiac-resynchronization therapy in heart failure with narrow QRS complexes. N Engl J Med 2007;357:2461-71 [17986493]

AMIOVIRT, 2003:

Strickberger SA, Hummel JD, Bartlett TG, Frumin HI, Schuger CD, Beau SL, Bitar C, Morady F Amiodarone versus implantable cardioverter-defibrillator: randomized trial in patients with nonischemic dilated cardiomyopathy and asymptomatic nonsustained ventricular tachycardia-AMIOVIRT. J Am Coll Cardiol 2003;41:1707-12 [12767651]

COMPANION (CRT+ICD vs MT), 2004:

Bristow MR, Saxon LA, Boehmer J, Krueger S, Kass DA, De Marco T, Carson P, DiCarlo L, DeMets D, White BG, DeVries DW, Feldman AM Cardiac-resynchronization therapy with or without an implantable defibrillator in advanced chronic heart failure. N Engl J Med 2004;350:2140-50 [15152059]

COMPANION (CRT+ICD vs CRT), 2004:

Bristow MR, Saxon LA, Boehmer J, Krueger S, Kass DA, De Marco T, Carson P, DiCarlo L, DeMets D, White BG, DeVries DW, Feldman AM Cardiac-resynchronization therapy with or without an implantable defibrillator in advanced chronic heart failure. N Engl J Med 2004;350:2140-50 [15152059]

MIRACLE-ICD-II, 2004:

Abraham WT, Young JB, Len AR, Adler S, Bank AJ, Hall SA, Lieberman R, Liem LB, O'Connell JB, Schroeder JS, Wheelan KR Effects of cardiac resynchronization on disease progression in patients with left ventricular systolic dysfunction, an indication for an implantable cardioverter-defibrillator, and mildly symptomatic chronic heart failure. *Circulation* 2004;110:2864-8 [15505095]

MADIT CRT, 2009:

Moss AJ, Hall WJ, Cannom DS, Klein H, Brown MW, Daubert JP, Estes NA 3rd, Foster E, Greenberg H, Higgins SL, Pfeffer MA, Solomon SD, Wilber D, Zareba W Cardiac-Resynchronization Therapy for the Prevention of Heart-Failure Events. *N Engl J Med* 2009 Sep 1;: [19723701] 10.1056/NEJMoa0906431

Goldenberg I, Kutiyafa V, Klein HU, Cannom DS, Brown MW, Dan A, Daubert JP, Estes NA 3rd, Foster E, Greenberg H, Kautzner J, Klempfner R, Kuniss M, Merkely B, Pfeffer MA, Quesada A, Viskin S, McNitt S, Polonsky B, Ghanem A, Solomon SD, Wilber D, Zareba W, Survival with Cardiac-Resynchronization Therapy in Mild Heart Failure. *N Engl J Med* 2014 Mar 30;: [24678999] 10.1056/NEJMoa1401426

RAFT, 2010:

Tang AS, Wells GA, Talajic M, Arnold MO, Sheldon R, Connolly S, Hohnloser SH, Nichol G, Birnie DH, Sapp JL, Yee R, Healey JS, Rouleau JL Cardiac-Resynchronization Therapy for Mild-to-Moderate Heart Failure. *N Engl J Med* 2010 Nov 14;: [21073365] 10.1056/NEJMoa1009540

Sapp JL, Parkash R, Wells GA, Yetisir E, Gardner MJ, Healey JS, Thibault B, Sterns LD, Birnie D, Nery PB, Sivakumaran S, Essebag V, Dorian P, Tang AS Cardiac Resynchronization Therapy Reduces Ventricular Arrhythmias in Primary but Not Secondary Prophylactic Implantable Cardioverter Defibrillator Patients: Insight From the Resynchronization in Ambulatory Heart Failure Trial. *Circ Arrhythm Electrophysiol* 2017;10: [28292754]

MIRACLE-ICD-I, 2003:

Young JB, Abraham WT, Smith AL, Leon AR, Lieberman R, Wilkoff B, Canby RC, Schroeder JS, Liem LB, Hall S, Wheelan K Combined cardiac resynchronization and implantable cardioversion defibrillation in advanced chronic heart failure: the MIRACLE ICD Trial. *JAMA* 2003;289:2685-94 [12771115]

CONTAK-CD , 2003:

Higgins SL, Hummel JD, Niazi IK, Giudici MC, Worley SJ, Saxon LA, Boehmer JP, Higginbotham MB, De Marco T, Foster E, Yong PG Cardiac resynchronization therapy for the treatment of heart failure in patients with intraventricular conduction delay and malignant ventricular tachyarrhythmias. *J Am Coll Cardiol* 2003;42:1454-9 [14563591]

2 prevention of sudden death

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
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

continued...

Trial	Treatments	Patients	Trials design and methods
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 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

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>

References

RethinQ, 2007:

Beshai JF, Grimm RA, Nagueh SF, Baker JH 2nd, Beau SL, Greenberg SM, Pires LA, Tchou PJ Cardiac-resynchronization therapy in heart failure with narrow QRS complexes. N Engl J Med 2007;357:2461-71 [17986493]

AMIOVIRT, 2003:

Strickberger SA, Hummel JD, Bartlett TG, Frumin HI, Schuger CD, Beau SL, Bitar C, Morady F Amiodarone versus implantable cardioverter-defibrillator: randomized trial in patients with nonischemic dilated cardiomyopathy and asymptomatic nonsustained ventricular tachycardia-AMIOVIRT. *J Am Coll Cardiol* 2003;41:1707-12 [12767651]

COMPANION (CRT+ICD vs MT), 2004:

Bristow MR, Saxon LA, Boehmer J, Krueger S, Kass DA, De Marco T, Carson P, DiCarlo L, DeMets D, White BG, DeVries DW, Feldman AM Cardiac-resynchronization therapy with or without an implantable defibrillator in advanced chronic heart failure. *N Engl J Med* 2004;350:2140-50 [15152059]

COMPANION (CRT+ICD vs CRT), 2004:

Bristow MR, Saxon LA, Boehmer J, Krueger S, Kass DA, De Marco T, Carson P, DiCarlo L, DeMets D, White BG, DeVries DW, Feldman AM Cardiac-resynchronization therapy with or without an implantable defibrillator in advanced chronic heart failure. *N Engl J Med* 2004;350:2140-50 [15152059]

MIRACLE-ICD-II, 2004:

Abraham WT, Young JB, Len AR, Adler S, Bank AJ, Hall SA, Lieberman R, Liem LB, O'Connell JB, Schroeder JS, Wheelan KR Effects of cardiac resynchronization on disease progression in patients with left ventricular systolic dysfunction, an indication for an implantable cardioverter-defibrillator, and mildly symptomatic chronic heart failure. *Circulation* 2004;110:2864-8 [15505095]

MIRACLE-ICD-I, 2003:

Young JB, Abraham WT, Smith AL, Leon AR, Lieberman R, Wilkoff B, Canby RC, Schroeder JS, Liem LB, Hall S, Wheelan K Combined cardiac resynchronization and implantable cardioversion defibrillation in advanced chronic heart failure: the MIRACLE ICD Trial. *JAMA* 2003;289:2685-94 [12771115]

CONTAK-CD , 2003:

Higgins SL, Hummel JD, Niazi IK, Giudici MC, Worley SJ, Saxon LA, Boehmer JP, Higginbotham MB, De Marco T, Foster E, Yong PG Cardiac resynchronization therapy for the treatment of heart failure in patients with intraventricular conduction delay and malignant ventricular tachyarrhythmias. *J Am Coll Cardiol* 2003;42:1454-9 [14563591]