

# Clinical trials of ICD

TrialResults-center [www.trialresultscenter.org](http://www.trialresultscenter.org)

## 1 acute myocardial infarction

Trial	Treatments	Patients	Trials design and methods
<b>early implantation of ICD after MI vs control</b>			
<b>IRIS , 2009</b> [NCT00157768] n=445/453 follow-up: 37 months	prophylactic ICD implantation early after myocardial infarction versus optimal medical therapy alone	patients patients at increased risk 5 to 31 days after AMI	Parallel groups open
<b>ICD vs no ICD</b>			
<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<=0.30	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<=0.35 and cardiac autonomic modulation (depressed heart rate variability or increased mean 24-hour heart rate)	Parallel groups open

More details and results :

- ICD for acute myocardial infarction in all type of patients at <http://www.trialresultscenter.org/go-Q353>

## References

### IRIS, 2009:

Steinbeck G, Andresen D, Seidl K, Brachmann J, Hoffmann E, Wojciechowski D, Kornacewicz-Jach Z, Sredniawa B, Lupkovics G, Hofgrtner F, Lubinski A, Rosenqvist M, Habets A, Wegscheider K, Senges J Defibrillator implantation early after myocardial infarction. N Engl J Med 2009;361:1427-36 [19812399]

### MADIT-II, 2002:

Moss AJ, Zareba W, Hall WJ, Klein H, Wilber DJ, Cannom DS, Daubert JP, Higgins SL, Brown MW, Andrews ML Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. N Engl J Med 2002;346:877-83 [11907286]

Goldenberg I, Gillespie J, Moss AJ, Hall WJ, Klein H, McNitt S, Brown MW, Cygankiewicz I, Zareba W Long-term benefit of primary prevention with an implantable cardioverter-defibrillator: an extended 8-year follow-up study of the multicenter automatic defibrillator implantation trial II. Circulation 2010;122:1265-71 [20837894]

[10.1161/CIRCULATIONAHA.110.940148](https://doi.org/10.1161/CIRCULATIONAHA.110.940148)

### DINAMIT, 2004:

Hohnloser SH, Kuck KH, Dorian P, Roberts RS, Hampton JR, Hatala R, Fain E, Gent M, Connolly SJ Prophylactic use of an implantable cardioverter-defibrillator after acute myocardial infarction. N Engl J Med 2004;351:2481-8 [[15590950](#)]

## 2 heart failure

Trial	Treatments	Patients	Trials design and methods
<b>Combined CRT + ICD vs no CRT</b>			
<b>RethinQ , 2007</b> [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
<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>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 >=3 wk before entry and EF <=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<=0.30	Parallel groups open
<b>CASH , 2000</b> n=99/189 follow-up: 57 months	ICD versus antiarrhythmic agents (amiodarone and metoprolol)	secondary prevention: survivors of cardiac arrest secondary to documented ventricular arrhythmias	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 <=0.30	Parallel groups open

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<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 ≤0.35	Parallel groups open
<b>AVID , 1997</b> [NCT00000531] n=507/509 follow-up: 18.2 months	ICD versus class III antiarrhythmic drugs, primarily amiodarone	secondary prevention: patients who had been resuscitated from near-fatal ventricular fibrillation or who had undergone cardioversion from sustained ventricular tachycardia	Parallel groups open
<b>CIDS , 2000</b> n=328/331 follow-up: 36 months	ICD versus amiodarone	secondary prevention: patients with resuscitated VF or VT or with unmonitored syncope	Parallel groups
<b>CABG-patch , 1997</b> [NCT00000540] n=446/454 follow-up: 32 months	ICD versus control	65279;patients undergoing CABG with EF ≤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 ≤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 ≤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 ≤0.35	Parallel groups open
<b>Combined CRT + ICD vs CRT</b>			

continued...

Trial	Treatments	Patients	Trials design and methods
<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>MADIT CRT , 2009</b> [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
<b>RAFT , 2010</b> [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
<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

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 survivors of cardiac arrest at <http://www.trialresultscenter.org/go-Q105>
- resynchronization (CRT) - defibrillators (ICD) for heart failure in post myocardial infarction at <http://www.trialresultscenter.org/go-Q106>

- 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](#)]

### **MADIT, 1996:**

Moss AJ, Hall WJ, Cannom DS, Daubert JP, Higgins SL, Klein H, Levine JH, Saksena S, Waldo AL, Wilber D, Brown MW, Heo M Improved survival with an implanted defibrillator in patients with coronary disease at high risk for ventricular arrhythmia. Multicenter Automatic Defibrillator Implantation Trial Investigators. *N Engl J Med* 1996;335:1933-40 [[8960472](#)]

### **MADIT-II, 2002:**

Moss AJ, Zareba W, Hall WJ, Klein H, Wilber DJ, Cannom DS, Daubert JP, Higgins SL, Brown MW, Andrews ML Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. *N Engl J Med* 2002;346:877-83 [[11907286](#)]

Goldenberg I, Gillespie J, Moss AJ, Hall WJ, Klein H, McNitt S, Brown MW, Cygankiewicz I, Zareba W Long-term benefit of primary prevention with an implantable cardioverter-defibrillator: an extended 8-year follow-up study of the multicenter automatic defibrillator implantation trial II. *Circulation* 2010;122:1265-71 [[20837894](#)]  
[10.1161/CIRCULATIONAHA.110.940148](#)

### **CASH, 2000:**

Kuck KH, Cappato R, Siebels J, Rppel R Randomized comparison of antiarrhythmic drug therapy with implantable defibrillators in patients resuscitated from cardiac arrest : the Cardiac Arrest Study Hamburg (CASH). *Circulation* 2000;102:748-54 [[10942742](#)]

### **CAT, 2002:**

Bnsch D, Antz M, Boczor S, Volkmer M, Tebbenjohanns J, Seidl K, Block M, Gietzen F, Berger J, Kuck KH Primary prevention of sudden cardiac death in idiopathic dilated cardiomyopathy: the Cardiomyopathy Trial (CAT). *Circulation* 2002;105:1453-8 [[11914254](#)]

### **DEFINITE, 2004:**

Kadish A, Dyer A, Daubert JP, Quigg R, Estes NA, Anderson KP, Calkins H, Hoch D, Goldberger J, Shalaby A, Sanders WE, Schaechter A, Levine JH Prophylactic defibrillator implantation in patients with nonischemic dilated cardiomyopathy. *N Engl J Med* 2004;350:2151-8 [[15152060](#)]

Albert CM, Quigg R, Saba S, Estes NA 3rd, Shaechter A, Subacius H, Howard A, Levine J, Kadish A Sex differences in outcome after implantable cardioverter defibrillator implantation in nonischemic cardiomyopathy. *Am Heart J* 2008;156:367-72 [[18657670](#)]

### **SCD-HeFT (ICD vs placebo), 2005:**

Bardy GH, Lee KL, Mark DB, Poole JE, Packer DL, Boineau R, Domanski M, Troutman C, Anderson J, Johnson G, McNulty SE, Clapp-Channing N, Davidson-Ray LD, Fraulo ES, Fishbein DP, Luceri RM, Ip JH Amiodarone or an implantable cardioverter-defibrillator for congestive heart failure. N Engl J Med 2005;352:225-37 [15659722]

**AVID, 1997:**

A comparison of antiarrhythmic-drug therapy with implantable defibrillators in patients resuscitated from near-fatal ventricular arrhythmias. The Antiarrhythmics versus Implantable Defibrillators (AVID) Investigators. N Engl J Med 1997;337:1576-83 [9411221]

**CIDS, 2000:**

Connolly SJ, Gent M, Roberts RS, Dorian P, Roy D, Sheldon RS, Mitchell LB, Green MS, Klein GJ, O'Brien B Canadian implantable defibrillator study (CIDS) : a randomized trial of the implantable cardioverter defibrillator against amiodarone. Circulation 2000;101:1297-302 [10725290]

**CABG-patch, 1997:**

Bigger JT Jr Prophylactic use of implanted cardiac defibrillators in patients at high risk for ventricular arrhythmias after coronary-artery bypass graft surgery. Coronary Artery Bypass Graft (CABG) Patch Trial Investigators. N Engl J Med 1997;337:1569-75 [9371853]

**DINAMIT, 2004:**

Hohnloser SH, Kuck KH, Dorian P, Roberts RS, Hampton JR, Hatala R, Fain E, Gent M, Connolly SJ Prophylactic use of an implantable cardioverter-defibrillator after acute myocardial infarction. N Engl J Med 2004;351:2481-8 [15590950]

**MUSIT, 1999:**

Buxton AE, Lee KL, Fisher JD, Josephson ME, Prystowsky EN, Hafley G A randomized study of the prevention of sudden death in patients with coronary artery disease. Multicenter Unsustained Tachycardia Trial Investigators. N Engl J Med 1999;341:1882-90 [10601507]

**SCD-HeFT (ICD vs amiodarone), 2005:**

Bardy GH, Lee KL, Mark DB, Poole JE, Packer DL, Boineau R, Domanski M, Troutman C, Anderson J, Johnson G, McNulty SE, Clapp-Channing N, Davidson-Ray LD, Fraulo ES, Fishbein DP, Luceri RM, Ip JH Amiodarone or an implantable cardioverter-defibrillator for congestive heart failure. N Engl J Med 2005;352:225-37 [15659722]

**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, Kutyifa 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]

### 3 prevention of sudden death

Trial	Treatments	Patients	Trials design and methods
<b>Combined CRT + ICD vs no CRT</b>			
<b>RethinQ , 2007</b> [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
<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>ICD vs no ICD</b>			
<b>Dutch trial , 1995</b> n=29/31 follow-up: 2 y	ICD versus conventional therapy	survivors of cardiac arrest caused by old myocardial infarction	

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</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>CASH , 2000</b> n=99/189 follow-up: 57 months	ICD versus antiarrhythmic agents (amiodarone and metoprolol)	secondary prevention: survivors of cardiac arrest secondary to documented ventricular arrhythmias	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
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<b>CIDS , 2000</b> n=328/331 follow-up: 36 months	ICD versus amiodarone	secondary prevention: patients with resuscitated VF or VT or with unmonitored syncope	Parallel groups
<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

continued...



<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<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<=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<=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<=0.35	Parallel groups open
<b>Combined CRT + ICD vs CRT</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

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 secondary prevention (survivors of cardiac arrest) at <http://www.trialresultscenter.org/go-Q108>

- resynchronization (CRT) - defibrillators (ICD) for prevention of sudden death in heart failure at <http://www.trialresultscenter.org/go-Q109>
- ICD for prevention of sudden death in primary prevention in post MI patients at <http://www.trialresultscenter.org/go-Q183>

## 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]

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### 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]

### Dutch trial, 1995:

Wever EF, Hauer RN, van Capelle FL, Tijssen JG, Crijns HJ, Algra A, Wiersfeld AC, Bakker PF, Robles de Medina EO Randomized study of implantable defibrillator as first-choice therapy versus conventional strategy in postinfarct sudden death survivors. *Circulation* 1995 Apr 15;91:2195-203 [7697849]

### MADIT, 1996:

Moss AJ, Hall WJ, Cannom DS, Daubert JP, Higgins SL, Klein H, Levine JH, Saksena S, Waldo AL, Wilber D, Brown MW, Heo M Improved survival with an implanted defibrillator in patients with coronary disease at high risk for ventricular arrhythmia. Multicenter Automatic Defibrillator Implantation Trial Investigators. *N Engl J Med* 1996;335:1933-40 [8960472]

### MADIT-II, 2002:

Moss AJ, Zareba W, Hall WJ, Klein H, Wilber DJ, Cannom DS, Daubert JP, Higgins SL, Brown MW, Andrews ML Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. *N Engl J Med* 2002;346:877-83 [11907286]

Goldenberg I, Gillespie J, Moss AJ, Hall WJ, Klein H, McNitt S, Brown MW, Cygankiewicz I, Zareba W Long-term benefit of primary prevention with an implantable cardioverter-defibrillator: an extended 8-year follow-up study of the multicenter automatic defibrillator implantation trial II. *Circulation* 2010;122:1265-71 [20837894]  
10.1161/CIRCULATIONAHA.110.940148

### CASH, 2000:

Kuck KH, Cappato R, Siebels J, Rppel R Randomized comparison of antiarrhythmic drug therapy with implantable defibrillators in patients resuscitated from cardiac arrest : the Cardiac Arrest Study Hamburg (CASH). *Circulation* 2000;102:748-54 [10942742]

### CAT, 2002:

Bnsch D, Antz M, Boczor S, Volkmer M, Tebbenjohanns J, Seidl K, Block M, Gietzen F, Berger J, Kuck KH Primary prevention of sudden cardiac death in idiopathic dilated cardiomyopathy: the Cardiomyopathy Trial (CAT). *Circulation* 2002;105:1453-8 [11914254]

### DEFINITE, 2004:

Kadish A, Dyer A, Daubert JP, Quigg R, Estes NA, Anderson KP, Calkins H, Hoch D, Goldberger J, Shalaby A, Sanders WE, Schaechter A, Levine JH Prophylactic defibrillator implantation in patients with nonischemic dilated cardiomyopathy. *N Engl J Med* 2004;350:2151-8 [[15152060](#)]

Albert CM, Quigg R, Saba S, Estes NA 3rd, Shaechter A, Subacius H, Howard A, Levine J, Kadish A Sex differences in outcome after implantable cardioverter defibrillator implantation in nonischemic cardiomyopathy. *Am Heart J* 2008;156:367-72 [[18657670](#)]

#### **SCD-HeFT (ICD vs placebo), 2005:**

Bardy GH, Lee KL, Mark DB, Poole JE, Packer DL, Boineau R, Domanski M, Troutman C, Anderson J, Johnson G, McNulty SE, Clapp-Channing N, Davidson-Ray LD, Fraulo ES, Fishbein DP, Luceri RM, Ip JH Amiodarone or an implantable cardioverter-defibrillator for congestive heart failure. *N Engl J Med* 2005;352:225-37 [[15659722](#)]

#### **AVID, 1997:**

A comparison of antiarrhythmic-drug therapy with implantable defibrillators in patients resuscitated from near-fatal ventricular arrhythmias. The Antiarrhythmics versus Implantable Defibrillators (AVID) Investigators. *N Engl J Med* 1997;337:1576-83 [[9411221](#)]

#### **CIDS, 2000:**

Connolly SJ, Gent M, Roberts RS, Dorian P, Roy D, Sheldon RS, Mitchell LB, Green MS, Klein GJ, O'Brien B Canadian implantable defibrillator study (CIDS) : a randomized trial of the implantable cardioverter defibrillator against amiodarone. *Circulation* 2000;101:1297-302 [[10725290](#)]

#### **CABG-patch, 1997:**

Bigger JT Jr Prophylactic use of implanted cardiac defibrillators in patients at high risk for ventricular arrhythmias after coronary-artery bypass graft surgery. Coronary Artery Bypass Graft (CABG) Patch Trial Investigators. *N Engl J Med* 1997;337:1569-75 [[9371853](#)]

#### **DINAMIT, 2004:**

Hohnloser SH, Kuck KH, Dorian P, Roberts RS, Hampton JR, Hatala R, Fain E, Gent M, Connolly SJ Prophylactic use of an implantable cardioverter-defibrillator after acute myocardial infarction. *N Engl J Med* 2004;351:2481-8 [[15590950](#)]

#### **MUSIT, 1999:**

Buxton AE, Lee KL, Fisher JD, Josephson ME, Prystowsky EN, Hafley G A randomized study of the prevention of sudden death in patients with coronary artery disease. Multicenter Unsustained Tachycardia Trial Investigators. *N Engl J Med* 1999;341:1882-90 [[10601507](#)]

#### **SCD-HeFT (ICD vs amiodarone), 2005:**

Bardy GH, Lee KL, Mark DB, Poole JE, Packer DL, Boineau R, Domanski M, Troutman C, Anderson J, Johnson G, McNulty SE, Clapp-Channing N, Davidson-Ray LD, Fraulo ES, Fishbein DP, Luceri RM, Ip JH Amiodarone or an implantable cardioverter-defibrillator for congestive heart failure. *N Engl J Med* 2005;352:225-37 [[15659722](#)]

#### **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]

## 4 ventricular tachycardia in patients with structural heart disease

Trial	Treatments	Patients	Trials design and methods
<b>catheter ablation before ICD vs no ablation</b>			
<b>VTACH , 2009</b> [NCT00919373] n=54/56 follow-up: 27 mo	catheter ablation for ventricular tachycardia (VT) plus implantable cardioverter defibrillator versus implantable cardioverter defibrillator alone	Patients undergoing implantation of an ICD Patients undergoing implantation of an ICD	Parallel groups open Europe
<b>SMASH-VT , 2007</b> [ISRCTN62488166] n=64/64 follow-up: 22.5 mo	defibrillator implantation with adjunctive catheter ablation versus defibrillator implantation alone	patients with a history of a myocardial infarction undergoing defibrillator implantation for spontaneous ventricular tachycardia or fibrillation	Parallel groups open

More details and results :

- catheter ablation of ventricular tachycardia for ventricular tachycardia in patients with structural heart disease in all type of patients at <http://www.trialresultscenter.org/go-Q382>

## References

#### VTACH, 2009:

Kuck KH, Schaumann A, Eckardt L, Willems S, Ventura R, Delacrtaz E, Pitschner HF, Kautzner J, Schumacher B, Hansen PS Catheter ablation of stable ventricular tachycardia before defibrillator implantation in patients with coronary heart disease (VTACH): a multicentre randomised controlled trial. Lancet 2010 Jan 2;375:31-40 [20109864] 10.1016/S0140-6736(09)61755-4

#### SMASH-VT, 2007:

Reddy VY, Reynolds MR, Neuzil P, Richardson AW, Taborsky M, Jongnarangsin K, Kralovec S, Sediva L, Ruskin JN, Josephson ME Prophylactic catheter ablation for the prevention of defibrillator therapy. N Engl J Med 2007;357:2657-65 [18160685]

## 5 patients with implantable cardioverter defibrillators

Trial	Treatments	Patients	Trials design and methods
<b>catheter ablation before ICD vs no ablation</b>			
<b>VTACH , 2009</b> [NCT00919373] n=54/56 follow-up: 27 mo	catheter ablation for ventricular tachycardia (VT) plus implantable cardioverter defibrillator versus implantable cardioverter defibrillator alone	Patients undergoing implantation of an ICD Patients undergoing implantation of an ICD	Parallel groups open Europe
<b>SMASH-VT , 2007</b> [ISRCTN62488166] n=64/64 follow-up: 22.5 mo	defibrillator implantation with adjunctive catheter ablation versus defibrillator implantation alone	patients with a history of a myocardial infarction undergoing defibrillator implantation for spontaneous ventricular tachycardia or fibrillation	Parallel groups open

More details and results :

- catheter ablation for patients with implantable cardioverter defibrillators in all type of patients at <http://www.trialresultscenter.org/go-Q384>

### References

#### **VTACH, 2009:**

Kuck KH, Schaumann A, Eckardt L, Willems S, Ventura R, Delacrtaz E, Pitschner HF, Kautzner J, Schumacher B, Hansen PS Catheter ablation of stable ventricular tachycardia before defibrillator implantation in patients with coronary heart disease (VTACH): a multicentre randomised controlled trial. Lancet 2010 Jan 2;375:31-40 [20109864] [10.1016/S0140-6736\(09\)61755-4](https://doi.org/10.1016/S0140-6736(09)61755-4)

#### **SMASH-VT, 2007:**

Reddy VY, Reynolds MR, Neuzil P, Richardson AW, Taborsky M, Jongnarangsin K, Kralovec S, Sediva L, Ruskin JN, Josephson ME Prophylactic catheter ablation for the prevention of defibrillator therapy. N Engl J Med 2007;357:2657-65 [18160685]

Entry terms: catheter ablation