Clinical trials of ICD

TrialResults-center www.trialresultscenter.org

1 acute myocardial infarction

Trial	Treatments	Patients	Trials design and methods
early implantation of ICD after MI vs control			
IRIS , 2009 [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
ICD vs no ICD			
MADIT-II , 2002 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
DINAMIT , 2004 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

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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
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
ICD vs no ICD			
MADIT , 1996 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
MADIT-II , 2002 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
CASH , 2000 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
CAT , 2002 n=50/54 follow-up: 66 months	ICD versus no iCD, conventional therapy	patients with recent onset nonischemic cardiomyopathy withEF <=0.30	Parallel groups open

continued...

Trial	Treatments	Patients	Trials design and methods
DEFINITE , 2004 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
SCD-HeFT (ICD vs placebo) , 2005 [NCT00000609] n=829/847 follow-up: 45.5 months	ICD versus optimized medical therapy	patients with ischemic and nonischemic cardiomyopathy withEF<=0.35	Parallel groups open
AVID , 1997 [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
CIDS , 2000 n=328/331 follow-up: 36 months	ICD versus amiodarone	secondary prevention: patients with resuscitated VF or VT or with unmonitored syncope	Parallel groups
CABG-patch , 1997 [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
DINAMIT , 2004 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
MUSIT , 1999 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
SCD-HeFT (ICD vs amiodarone) , 2005 [NCT00000609] n=829/845 follow-up: 45.5 months	ICD versus optimized medical therapy with amiodarone	patients with ischemic and nonischemic cardiomyopathy withEF<=0.35	Parallel groups open
Combined CRT + ICD vs CRT			

continued...

Trial	Treatments	Patients	Trials design and methods
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
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 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 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 mildy symptomatic heart failure with prolonged QRS interval at http://www.trialresultscenter.org/go-Q349

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3 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
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
ICD vs no ICD			
Dutch trial , 1995 n=29/31 follow-up: 2 y	ICD versus conventional therapy	survivors of cardiac arrest caused by old myocardial infarction	

continued...

Trial	Treatments	Patients	Trials design and methods
MADIT , 1996 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
MADIT-II , 2002 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
CASH , 2000 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
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AVID , 1997 [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
CIDS , 2000 n=328/331 follow-up: 36 months	ICD versus amiodarone	secondary prevention: patients with resuscitated VF or VT or with unmonitored syncope	Parallel groups
CABG-patch , 1997 [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

continued...

Trial	Treatments	Patients	Trials design and methods
DINAMIT , 2004 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
MUSIT , 1999 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
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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

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

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4 ventricular tachycardia in patients with structural heart disease

Trial	Treatments	Patients	Trials design and methods
catheter ablation before ICD vs no ablation			
VTACH , 2009 [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
SMASH-VT , 2007 [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

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5 patients with implantable cardioverter defibrillators

Trial	Treatments	Patients	Trials design and methods
catheter ablation before ICD vs no ablation			
VTACH , 2009 [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
SMASH-VT , 2007 [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

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Entry terms: catheter ablation