

Clinical trials of amiodarone

TrialResults-center www.trialresultscenter.org

1 post myocardial infarction

Trial	Treatments	Patients	Trials design and methods
early amiodarone vs control			
BASIS , 1990 n=98/14 follow-up: 65279;12 mo	amiodarone 1 g for 5 d; then 200 mg/d started within 4 weeks of AMI versus no amiodarone (usual care)	patients with persisting asymptomatic complex arrhythmias after myocardial infarction (Lown class 3 or 4b in >2 of 24 h)	Parallel groups open
Navarro-Lopez , 1993 n=115/123 follow-up: 24 mo	amiodarone 600 mg/d for 1 week, 400 mg/d for 1 week then 200 mg/d started 10-30 d after AMI versus no amiodarone	patients who have had MI with a left ventricular ejection fraction of 20 to 45% and >or = 3 ventricular premature complexes per hour (pairs or runs) - 3 VPOs/h, pairs or runs of VT	Parallel groups open Spain
early amiodarone vs placebo			
CAMIAT , 1991 n=NA follow-up: 24 mo	amiodarone 10 mg/kg per d for 3 weeks then 300-400 mg/d started 6-45 d after AMI versus placebo	patients with acute myocardial infarction within the previous 6-30 days and >10 VPDs/h for 18 h or a run of VT	Parallel groups double blind
Ceremuzynski , 1992 n=305/308 follow-up: 12 mo	amiodarone 800 mg/d for 1 week then 200-400 mg/d started 5-7 d after AMI versus placebo	No need for antiarrhythmic therapy	Parallel groups double blind
Hockings , 1987 n=59/70 follow-up: 642 mo	amiodarone 200 mg 3 times daily for 1 wk; then 200 mg/d started <8-10 d after AMI versus placebo	patients with AMI - Absence of VF or VT >3 beats	Parallel groups double blind

More details and results :

- antiarrhythmic drugs for post myocardial infarction in all type of patients at <http://www.trialresultscenter.org/go-Q251>

References

BASIS, 1990:

Burkart F, Pfisterer M, Kiowski W, Follath F, Burckhardt D Effect of antiarrhythmic therapy on mortality in survivors of myocardial infarction with asymptomatic complex ventricular arrhythmias: Basel Antiarrhythmic Study of Infarct Survival (BASIS) J Am Coll Cardiol 1990;16:1711-8 [2254558]

Navarro-Lopez, 1993:

Navarro-Lopez F, Cosin J, Marrugat J, Guindo J, Bayes de Luna A Comparison of the effects of amiodarone versus metoprolol on the frequency of ventricular arrhythmias and on mortality after acute myocardial infarction. SSSD Investigators. Spanish Study on Sudden Death. Am J Cardiol 1993;72:1243-8 [7504880]

CAMIAT , 1991:

Cairns JA, Connolly SJ, Gent M, Roberts R Post-myocardial infarction mortality in patients with ventricular premature depolarizations. Canadian Amiodarone Myocardial Infarction Arrhythmia Trial Pilot Study. Circulation 1991;84:550-7 [1860199]

Ceremuzynski, 1992:

Ceremuzynski L, Kleczar E, Krzeminska-Pakula M, Kuch J, Nartowicz E, Smielak-Korombel J, Dydzyszynski A, Maciejewicz J, Zaleska T, Lazarczyk-Kedzia E Effect of amiodarone on mortality after myocardial infarction: a double-blind, placebo-controlled, pilot study. J Am Coll Cardiol 1992;20:1056-62 [1401602]

Hockings, 1987:

Hockings BE, George T, Mahrous F, Taylor RR, Hajar HA Effectiveness of amiodarone on ventricular arrhythmias during and after acute myocardial infarction. Am J Cardiol 1987;60:967-70 [3673913]

2 heart failure

2

Trial	Treatments	Patients	Trials design and methods
amiodarone vs no treatment			
GESICA , 1994 n=260/256 follow-up: 110 years	amiodarone 300 mg/day versus no treatment	patients with severe heart failure Any two of CTR >0.55, LVEF<=35% , echo LVED >32 cm/m2	open
EPAMSA , 1985 n=66/61 follow-up: 081 years	amiodarone 400 mg/day versus no treatment	patients with reduced left ventricular ejection fraction (<35%) and asymptomatic ventricular arrhythmias (Lown classes 2 and 4) LVEF <=35% and Lown class 25	open
amiodarone vs placebo			
Nicklas , 1991 n=101 follow-up: NA	amiodarone 200 mg/day versus placebo	patients with ejection fractions less than 30% , New York Heart Association class III or IV symptoms, and frequent but asymptomatic spontaneous ventricular ectopy (Lown class II to V) LVEF <=30% and Lown class 25	double blind
Hamer , 1989 n=34 follow-up: 163 years	amiodarone 200 mg/day versus placebo	patients with severe congestive heart failure but no sustained ventricular arrhythmia	double blind

continued...

Trial	Treatments	Patients	Trials design and methods
STATCHF , 1995 n=674 follow-up: 215 years	amiodarone 200 mg/day versus placebo	patients with symptoms of congestive heart failure, cardiac enlargement, 10 or more premature ventricular contractions per hour, and a left ventricular ejection fraction of 40 percent or less LVEF <=40% and >=10 VPD/h and LVED >=55 mm or CTR >055	double blind
amiodarone vs ICD			
AMIOVIRT , 2003 n=52/51 follow-up: 2 y	amiodarones versus implantable cardioverter-defibrillatorag	patients with nonischemic dilated cardiomyopathy, asymptomatic nonsustained ventricular tachycardia, and left ventricular ejection fraction <=0.35	Parallel groups US

More details and results :

- antiarrhythmic drugs for heart failure in all type of heart failure at <http://www.trialresultscenter.org/go-Q46>

References

∞

GESICA, 1994:

Doval HC, Nul DR, Grancelli HO, Perrone SV, Bortman GR, Curiel R Randomised trial of low-dose amiodarone in severe congestive heart failure. Grupo de Estudio de la Sobrevida en la Insuficiencia Cardiaca en Argentina (GESICA) Lancet 1994;344:493-8 [7914611]

EPAMSA, 1985:

Garguichevich JJ, Ramos JL, Gambarte A, Gentile A, Hauad S, Scapin O, Sirena J, Tibaldi M, Toplikar J Effect of amiodarone therapy on mortality in patients with left ventricular dysfunction and asymptomatic complex ventricular arrhythmias: Argentine Pilot Study of Sudden Death and Amiodarone (EPAMSA). Am Heart J 1995;130:494-500 [7661066]

Nicklas, 1991:

Nicklas JM, McKenna WJ, Stewart RA, Mickelson JK, Das SK, Schork MA, Krikler SJ, Quain LA, Morady F, Pitt B Prospective, double-blind, placebo-controlled trial of low-dose amiodarone in patients with severe heart failure and asymptomatic frequent ventricular ectopy. Am Heart J 1991;122:1016-21 [1927852]

Hamer, 1989:

Hamer AW, Arkles LB, Johns JA Beneficial effects of low dose amiodarone in patients with congestive cardiac failure: a placebo-controlled trial. J Am Coll Cardiol 1989;14:1768-74 [2685081]

STATCHF, 1995:

Singh SN, Fletcher RD, Fisher SG, Singh BN, Lewis HD, Deedwania PC, Massie BM, Colling C, Lazzeri D Amiodarone in patients with congestive heart failure and asymptomatic ventricular arrhythmia. Survival Trial of Antiarrhythmic Therapy in Congestive Heart Failure. N Engl J Med 1995;333:77-82 [7539890]

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 May 21;41:1707-12 [12767651]

3 atrial fibrillation

Trial	Treatments	Patients	Trials design and methods
amiodarone vs placebo			
Channer , 2004 n=61/38 follow-up: 12 months	Amiodarone 200 mg/d versus placebo	patients with Persistent AF	Parallel groups double blind
GEFACA , 2001 n=35/15 follow-up: 16 months	Amiodarone 200 mg/d versus placebo	Persistent AF lasting >2 months	Parallel groups double blind
Kochiadakis (amiodarone vs placebo) , 2000 n=65/60 follow-up: 24 months	Amiodarone 200 mg/d versus placebo	Any documented symptomatic previous or persistent AF	Parallel groups single
SAFE-T (amiodarone vs placebo) , 2005 n=267/137 follow-up: 12 months	Amiodarone 300 mg/d versus placebo	Persistent AF lasting 3 days to 1 year	Parallel groups double blind
amiodarone vs class I drugs			
AFFIRM Substudy (amiodarone vs class I drugs) , 2003 n=106/116 follow-up: 12 months, and 3.8y	Amiodarone 200 mg/d , versus class I drugs	patients with AF likely to be recurrent and to cause illness or deathpj	Parallel groups open US, Canada
AFFIRM Substudy (sotalol vs class I drugs) , 2003 n=NA follow-up: 12 months, and 3.8y	Amiodarone 200 mg/d , , sotalol versus class I drugs	patients with AF likely to be recurrent and to cause illness or deathpj	Parallel groups open
amiodarone vs disopyramide			
Villani , 1992 n=35/41 follow-up: 14 months	Amiodarone 200 mg/d versus disopyramide 500 mg/d	Symptomatic recent-onset AF lasting >1 hour, being at least the second episode	Parallel groups open
amiodarone vs propafenone			

continued...

Trial	Treatments	Patients	Trials design and methods
Kochiadakis a , 2004 n=72/74 follow-up: 24 months	Amiodarone 200 mg/d versus propafenone 450 mg/d	Any documented symptomatic previous or persistent AF	Parallel groups single
amiodarone vs quinidine			
Vitolo , 1981 n=28/26 follow-up: 6 months	Amiodarone 400 mg/d versus Quinidine 1,2 g/d	Any persistent AF	Parallel groups open
amiodarone vs sotalol			
AFFIRM Substudy (amiodarone vs sotalol) , 2003 n=131/125 follow-up: mean 3.8y	Amiodarone 200 mg/d versus Sotalol 240 mg/d	patients with AF likely to be recurrent and to cause illness or deathpj	Parallel groups open
Kochiadakis (amiodarone vs sotalol) , 2000 n=65/61 follow-up: 24 months	Amiodarone 200 mg/d , Amiodarone 200 mg/d versus	Any documented symptomatic previous or persistent AF	Parallel groups single
SAFE-T (amiodarone vs sotalol) , 2005 n=267/261 follow-up: 12 months	Amiodarone 300 mg/d , Amiodarone 300 mg/d versus	Persistent AF lasting 3 days to 1 year	Parallel groups double blind

More details and results :

- antiarrhythmic drugs for atrial fibrillation in maintaining sinus rhythm after cardioversion at <http://www.trialresultscenter.org/go-Q113>

References

Channer, 2004:

Channer KS, Birchall A, Steeds RP, Walters SJ, Yeo WW, West JN, Muthusamy R, Rhoden WE, Saeed BT, Batin P, Brooksby WP, Wilson I, Grant S A randomized placebo-controlled trial of pre-treatment and short- or long-term maintenance therapy with amiodarone supporting DC cardioversion for persistent atrial fibrillation. Eur Heart J 2004;25:144-50 [14720531]

GEFACA, 2001:

Galpern J, Elizari MV, Chiale PA, Molina RT, Ledesma R, Scapn AO, Vzquez Blanco M Efficacy of amiodarone for the termination of chronic atrial fibrillation and maintenance of normal sinus rhythm: a prospective, multicenter, randomized, controlled, double blind trial. J Cardiovasc Pharmacol Ther 2001;6:341-50 [11907636]

Kochiadakis (amiodarone vs placebo), 2000:

Kochiadakis GE, Igoumenidis NE, Marketou ME, Kaleboubas MD, Simantirakis EN, Vardas PE Low dose amiodarone and sotalol in the treatment of recurrent, symptomatic atrial fibrillation: a comparative, placebo controlled study. Heart 2000;84:251-7 [10956284]

Kochiadakis GE, Igoumenidis NE, Marketou ME, Solomou MC, Kanoupakis EM, Vardas PE Low-dose amiodarone versus sotalol for suppression of recurrent symptomatic atrial fibrillation. *Am J Cardiol* 1998;81:995-8 [[9576159](#)]

Kochiadakis GE, Marketou ME, Igoumenidis NE, Chrysostomakis SI, Mavrakis HE, Kaleboubas MD, Vardas PE Amiodarone, sotalol, or propafenone in atrial fibrillation: which is preferred to maintain normal sinus rhythm? *Pacing Clin Electrophysiol* 2000;23:1883-7 [[11139949](#)]

SAFE-T (amiodarone vs placebo), 2005:

Singh BN, Singh SN, Reda DJ, Tang XC, Lopez B, Harris CL, Fletcher RD, Sharma SC, Atwood JE, Jacobson AK, Lewis HD Jr, Raisch DW, Ezekowitz MD Amiodarone versus sotalol for atrial fibrillation. *N Engl J Med* 2005;352:1861-72 [[15872201](#)]

Singh SN, Singh BN, Reda DJ, Fye CL, Ezekowitz MD, Fletcher RD, Sharma SC, Atwood JE, Jacobson AK, Lewis HD Jr, Antman EM, Falk RH, Lopez B, Tang XC Comparison of sotalol versus amiodarone in maintaining stability of sinus rhythm in patients with atrial fibrillation (Sotalol-Amiodarone Fibrillation Efficacy Trial [Safe-T]). *Am J Cardiol* 2003;92:468-72 [[12914883](#)]

AFFIRM Substudy (amiodarone vs class I drugs), 2003:

J Am Coll Cardiol 2003;42:20-9 [[12849654](#)]

AFFIRM Substudy (sotalol vs class I drugs), 2003:

J Am Coll Cardiol 2003;42:20-9 [[12849654](#)]

Villani, 1992:

Villani R, Zoletti F, Veniani M, Locati F, Nava S [A comparison between amiodarone and disopyramide in a delayed-release formulation in the prevention of recurrences of symptomatic atrial fibrillation] *Clin Ter* 1992;140:35-9 [[1559321](#)]

Kochiadakis a, 2004:

Kochiadakis GE, Igoumenidis NE, Hamilos ME, Tzerakis PG, Klapsinos NC, Chlouverakis GI, Vardas PE Sotalol versus propafenone for long-term maintenance of normal sinus rhythm in patients with recurrent symptomatic atrial fibrillation. *Am J Cardiol* 2004;94:1563-6 [[15589019](#)]

Kochiadakis GE, Igoumenidis NE, Hamilos MI, Tzerakis PG, Klapsinos NC, Zacharis EA, Vardas PE Long-term maintenance of normal sinus rhythm in patients with current symptomatic atrial fibrillation: amiodarone vs propafenone, both in low doses. *Chest* 2004;125:377-83 [[14769712](#)]

Vitolo, 1981:

Vitolo E, Tronci M, Larovere MT, Rumolo R, Morabito A Amiodarone versus quinidine in the prophylaxis of atrial fibrillation. *Acta Cardiol* 1981;36:431-44 [[7039195](#)]

AFFIRM Substudy (amiodarone vs sotalol), 2003:

Maintenance of sinus rhythm in patients with atrial fibrillation: an AFFIRM substudy of the first antiarrhythmic drug. *J Am Coll Cardiol* 2003;42:20-9 [[12849654](#)]

Kochiadakis (amiodarone vs sotalol), 2000:

Kochiadakis GE, Igoumenidis NE, Marketou ME, Kaleboubas MD, Simantirakis EN, Vardas PE *Heart* 2000;84:251-7 [[10956284](#)]

SAFE-T (amiodarone vs sotalol), 2005:

Singh BN, Singh SN, Reda DJ, Tang XC, Lopez B, Harris CL, Fletcher RD, Sharma SC, Atwood JE, Jacobson AK, Lewis HD Jr, Raisch DW, Ezekowitz MD *N Engl J Med* 2005;352:1861-72 [[15872201](#)] [10.1056/NEJMoa041705](#)

4 cardiac arrest

Trial	Treatments	Patients	Trials design and methods
amiodarone vs placebo			
ARREST , 1999 n=246/258 follow-up:	intravenous amiodarone 300mg versus placebo	Patients with cardiac arrest by ventricular fibrillation (or pulseless ventricular tachycardia) and not resuscitated after receiving three or more precordial shocks	double blind
amiodarone vs lidocaine			
ALIVE , 2002 n=180/167 follow-up: 1 day	intravenous amiodarone plus lidocaine placebo versus intravenous lidocaine plus amiodarone placebo	out-of-hospital ventricular fibrillation resistant to three shocks, intravenous epinephrine, and a further shock; or recurrent ventricular fibrillation after initially successful defibrillation	double blind

More details and results :

- antiarrhythmic drugs for cardiac arrest in out hospital patients at <http://www.trialresultscenter.org/go-Q182>

References

ARREST, 1999:

Kudenchuk PJ, Cobb LA, Copass MK, Cummins RO, Doherty AM, Fahrenbruch CE, Hallstrom AP, Murray WA, Olsufka M, Walsh T Amiodarone for resuscitation after out-of-hospital cardiac arrest due to ventricular fibrillation. N Engl J Med 1999 Sep 16;341:871-8 [10486418]

ALIVE, 2002:

Dorian P, Cass D, Schwartz B, Cooper R, Gelaznikas R, Barr A Amiodarone as compared with lidocaine for shock-resistant ventricular fibrillation. N Engl J Med 2002 Mar 21;346:884-90 [11907287]

Entry terms: Amiobeta, Cordarone, Cordarex, Amiodarex, Kordaron, Trangorex, Amiodarona, Amiohexal, Braxan, Corbionax, Ortacrone, Rytmarone, Tachydaron, Aratac