Clinical trials of amiodarone

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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 :

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

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2 heart failure

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 >055, 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

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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 :

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

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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 ilness 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 ilness 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			

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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 ilness 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 :

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

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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 :

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

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