

# Clinical trials of amiodarone

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## 1 post myocardial infarction

Trial	Treatments	Patients	Trials design and methods
<b>early amiodarone vs control</b>			
<a href="#">BASIS , 1990</a> 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
<a href="#">Navarro-Lopez , 1993</a> 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
<b>early amiodarone vs placebo</b>			
<a href="#">CAMIAT , 1991</a> 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
<a href="#">Ceremuzynski , 1992</a> 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
<a href="#">Hockings , 1987</a> 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

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## 2 heart failure

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Trial	Treatments	Patients	Trials design and methods
<b>amiodarone vs no treatment</b>			
<b>GESICA , 1994</b> 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
<b>EPAMSA , 1985</b> 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
<b>amiodarone vs placebo</b>			
<b>Nicklas , 1991</b> 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
<b>Hamer , 1989</b> 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
<b>STATCHF , 1995</b> 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
<b>amiodarone vs ICD</b>			
<b>AMIOVIRT , 2003</b> 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>

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### 3 atrial fibrillation

Trial	Treatments	Patients	Trials design and methods
<b>amiodarone vs placebo</b>			
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
<b>amiodarone vs class I drugs</b>			
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
<b>amiodarone vs disopyramide</b>			
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
<b>amiodarone vs propafenone</b>			

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<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
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
<b>amiodarone vs quinidine</b>			
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
<b>amiodarone vs sotalol</b>			
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>

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

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## **4 cardiac arrest**

Trial	Treatments	Patients	Trials design and methods
<b>amiodarone vs placebo</b>			
<b>ARREST , 1999</b> 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
<b>amiodarone vs lidocaine</b>			
<b>ALIVE , 2002</b> 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>

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