

Clinical trials of antiarrhythmic drugs for atrial fibrillation in maintaining sinus rhythm after cardioversion

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1 amiodarone/dronedarone

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
dronedarone vs placebo			
PALLAS , 2011 [NCT01151137] n=1577/1572 follow-up: 3 years	Dronedarone versus placebo	patients with permanent atrial fibrillation and additional risk factors	Parallel groups double-blind
ADONIS , 2007 [NCT00259376] n=417/208 follow-up: 12 months	dronedarone 400 mg twice daily versus placebo	patients with at least one episode of atrial fibrillation in the preceding 3 months, and in sinus rhythm for at least 1 hour before randomization	Parallel groups double blind United States, Canada, Australia, South Africa, Argentina
ATHENA , 2009 [NCT00174785] n=2301/2327 follow-up: 21.5 months	dronedarone 400 mg twice a day versus placebo	patients (>70y) with paroxysmal or persistent atrial fibrillation and additional risk factors for death	Parallel groups double blind 37 countries
DAFNE , 2003 n=151/48 follow-up:	Dronedarone various doses (800, 1200, 1600 mg/d) versus placebo	patients with Persistent AF	Parallel groups double blind

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Trial	Treatments	Patients	Trials design and methods
EURIDIS , 2007 [NCT00259428] n=411/201 follow-up: 12 months	dronedarone 400 mg twice daily versus placebo	patients with at least one episode of atrial fibrillation in the preceding 3 months, and in sinus rhythm for at least 1 hour before randomization	Parallel groups double blind 12 European countries
EURIDIS ADONIS (pooled analysis) , 2009 n=828/409 follow-up: 12 months	Dronedarone 800 mg/d versus placebo	AF documented in the previous 3 months	Parallel groups double blind Europe, US, canada, Australia, South A, Argentina
dronedarone vs amiodarone			
DIONISOS , 2007 [NCT00489736] n=249/255 follow-up: 6 months	Dronedarone (400mg BID) versus Amiodarone (600mg daily for 28 days, then 200mg daily thereafter)	Patients with documented atrial fibrillation for more than 72 hours for whom cardioversion and antiarrhythmic treatment is indicated in the opinion of the investigator and under oral anticoagulation	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			
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

continued...

Trial	Treatments	Patients	Trials design and methods
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

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DIONISOS, 2007:

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

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

Villani, 1992:

Kochiadakis a, 2004:

Vitolo, 1981:

AFFIRM Substudy (amiodarone vs sotalol), 2003:

Kochiadakis (amiodarone vs sotalol), 2000:

SAFE-T (amiodarone vs sotalol), 2005:

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2 Class Ia

Trial	Treatments	Patients	Trials design and methods
quinidine vs no treatment			
Hillestad , 1971 n=NA	-	-	Parallel groups
Sodermark , 1975 n=110/75 follow-up: 12 months	Quinidine 1.2 - 1.8 g/d versus no treatment	Persistent AF or AF1 lasting <3 year	Parallel groups open
disopyramide vs placebo			
Karlson , 1998 n=46/46 follow-up: 12 months	Disopyramide 500 mg/d versus palcebo	Persistent AF between 6 weeks and 1 year	Parallel groups open
Lloyd (Disopyramide vs placebo) , 1984 n=29/25 follow-up: 6 months	Disopyramide 450 mg/d , versus placebo	Persistent AF lasting 1 month to 3 years	Parallel groups double blind
quinidine vs placebo			

continued...

Trial	Treatments	Patients	Trials design and methods
Byrne Quinn , 1979 n=32/42 follow-up: 12 months	Quinidine 1.2 g/d versus placebo	Persistent AF	Parallel groups double blind
Lloyd (quinidine vs placebo) , 1984 n=NA follow-up: 6 months	quinidine 1.4 g/d versus placebo	Persistent AF lasting 1 month to 3 years	Parallel groups double blind
PAFAC (quinidine vs placebo) , 2004 n=377/88 follow-up: 12 months	Quinidine 0,480 g/d (+ verapamil) versus placebo	Persistent AF lasting >7 daysil	Parallel groups double blind
SOPAT (quinidine vs placebo) , 2004 n=518/251 follow-up: 12 months	Quinidine 0,320 or 0,480 g/d (+ verapamil) versus placebo	Paroxysmal AF documented in the last 1 month@4	Parallel groups double blind
quinidine vs digoxin			
Steinbeck (quinidine vs digoxin) , 1988 n=15/15 follow-up: 12 months	Quinidine 1 g/d (+ digoxine) versus digoxine alone	Paroxysmal symptomatic AF of any duration	Parallel groups open
quinidine vs disopyramide			
Lloyd (quinidine vs disopyramide) , 1984 n=28/29 follow-up: 6 months	quinidine 1.4 g/d , quinidine 1.4 g/d versus	Persistent AF lasting 1 month to 3 years	Parallel groups double blind
quinidine vs flecainide			
Steinbeck (quinidine vs flecainide) , 1988 n=15/15 follow-up: 12 months	Quinidine 1 g/d (+ digoxine) , Quinidine 1 g/d (+ digoxine) versus	Paroxysmal symptomatic AF of any duration	Parallel groups open
disopyramide vs propafenone			
PRODIS , 1996 n=31/25 follow-up: 6 months	Disopyramide 750 mg/d versus propafenone 900 mg/d	Persistent AF	Parallel groups double blind
disopyramide vs quinidine			
Lloyd (Disopyramide vs quinidine) , 1984 n=29/28 follow-up: 6 months	Disopyramide 450 mg/d , , versus placebo	Persistent AF lasting 1 month to 3 years	Parallel groups double blind
quinidine vs sotalol			
Hohnloser , 1995 n=25/25 follow-up: 6 months	Quinidine 1 g/d versus sotalol 240-320 mg/dt	Persistent AF between 2 days and 6 months	Parallel groups open

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Trial	Treatments	Patients	Trials design and methods
Juul-Moller , 1990 n=85/98 follow-up: 6 months	Quinidine 1,2 g/d versus Sotalol 160-320 mg/dt	Persistent AF between 2 months and 1 year	Parallel groups open
Kalusche , 1994 n=41/41 follow-up: 12 months	Quinidine 1 g/d versus Sotalol 240-400 mg/dt	AF lasting from 2 weeks to 2 years	Parallel groups open
PAFAC (quinidine vs sotalol) , 2004 n=377/383 follow-up: 12 months	Quinidine 0,480 g/d (+ verapamil , Quinidine 0,480 g/d (+ verapamil versus	Persistent AF lasting >7 daysil	Parallel groups double blind
SOCESP , 1999 n=63/58 follow-up: 6 months	Quinidine 700 mg/d versus sotalol 240 mg/d	AF lasting <6 months	Parallel groups open
SOPAT (quinidine vs sotalol) , 2004 n=518/264 follow-up: 12 months	Quinidine 0,320 or 0,480 g/d (+ verapamil) , Quinidine 0,320 or 0,480 g/d (+ verapamil) versus	Paroxysmal AF documented in the last 1 month@4	Parallel groups double blind

References

Hillestad, 1971:

Sodermark, 1975:

Karlson, 1998:

Lloyd (Disopyramide vs placebo), 1984:

Byrne Quinn, 1979:

Lloyd (quinidine vs placebo), 1984:

PAFAC (quinidine vs placebo), 2004:

SOPAT (quinidine vs placebo), 2004:

Steinbeck (quinidine vs digoxin), 1988:

Lloyd (quinidine vs disopyramide), 1984:

Steinbeck (quinidine vs flecainide), 1988:

PRODIS, 1996:

Lloyd (Disopyramide vs quinidine), 1984:

Hohnloser, 1995:

Juul-Moller, 1990:

Kalusche, 1994:

PAFAC (quinidine vs sotalol), 2004:

SOCESP, 1999:

SOPAT (quinidine vs sotalol), 2004:

3 Class Ic

Trial	Treatments	Patients	Trials design and methods
flecainide vs no treatment			
Van Gelder , 1989 n=36/37 follow-up: 12 months	Flecainide 200-300 mg/d versus no treatment	Any persistent AF or AFL	Parallel groups open
flecainide vs placebo			
Carunchio (flecainide vs placebo) , 1995 n=20/26 follow-up: 12 months	Flecainide 200 mg/d versus placebo	patients with recurrent AF with >3 episodes in previous 1 year	Parallel groups open
propafenone vs placebo			
Bellandi (propafenone vs placebo) , 2001 n=102/92 follow-up: 12 months	Propafenone 900 mg/d/d after pharmacological or electrical cardioversion versus placebo	patients with paroxysmal recurrent or persistent AF	Parallel groups double blind
Dogan , 2004 n=58/52 follow-up: 15 months	Propafenone 450 mg/d versus placebo	AF of duration 3 hours to 3 months ???	Parallel groups single
Kochiadakis b (propafenone vs placebo) , 2004 n=86/83 follow-up: 24 months	Propafenone 450 mg/d versus placebo	Any documented symptomatic previous or persistent AF	Parallel groups single
RAFT , 2003 n=397/126 follow-up: 9 months	Propafenone at various doses (450, 650, 850 mg/d) versus placebo.	Previous symptomatic AF documented in the last year	Parallel groups double blind
Stroobandt , 1997 n=77/25 follow-up: 6 months	Propafenone 450 mg/d versus placebo	Recent-onset AF or persistent AF lasting >2 weeks	Parallel groups double blind
flecainide vs digoxin			
Steinbeck (flecainide vs digoxin) , 1988 n=15/15 follow-up: 12 months	-	Paroxysmal symptomatic AF of any duration	Parallel groups open
propafenone vs flecainide			
FAPIS , 1996 n=97/103 follow-up: 12 months	propafenone 520 mg/dt versus Flecainide 200 mg/d	Paroxysmal recurrent AF with >2 episodes in the last 4 months	Parallel groups open
flecainide vs propafenone			
Aliot , 1996 n=48/49 follow-up: 12 months	Flecainide 100-200mg/d versus Propafenone 600 mg/d	patients with paroxysmal AF documented any time before	Parallel groups open
flecainide vs quinidine			

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Trial	Treatments	Patients	Trials design and methods
Naccarelli , 1996 n=117/122 follow-up: 12 months	Flecainide 200-300 mg/d versus Quinidine 1-1,5 g/d	Any documented symptomatic AF	Parallel groups double blind
propafenone vs quinidine			
Richiardi , 1992 n=98/102 follow-up: 12 months	Propafenone 900 mg/d versus Quinidine 1 g/d mg/d	Paroxysmal AF having >3 episodes in the last 3 months	Parallel groups open
propafenone vs sotalol			
Reimold , 1993 n=50/50 follow-up: 12 months	Propafenone 675 mg/d versus Sotalol 320 mg/d	Any symptomatic AF or AFbx-bitm	Parallel groups open

References

Van Gelder, 1989:

Carunchio (flecainide vs placebo), 1995:

Bellandi (propafenone vs placebo), 2001:

Dogan, 2004:

Kochiadakis b (propafenone vs placebo), 2004:

RAFT, 2003:

Stroobandt, 1997:

Steinbeck (flecainide vs digoxin), 1988:

FAPIS, 1996:

Aliot, 1996:

Naccarelli, 1996:

Richiardi, 1992:

Reimold, 1993:

4 Class II: Beta-blockers

Trial	Treatments	Patients	Trials design and methods
metoprolol vs placebo			
Kuhlkamp , 2000 n=197/197 follow-up: 6 months	Metoprolol 100 mg/d versus placebo	Persistent AF lasting 2 days to 1 year	Parallel groups double blind

References

Kuhlkamp, 2000:

5 Class III

Trial	Treatments	Patients	Trials design and methods
Azimilide vs placebo			
ASAP , 2003 n=891/489 follow-up: 6 months	Azimilide various doses (35 to 125 mg/d) after pharmacological or electrical cardioversion versus placebo	patients with previous AF documented in the last 2 years	Parallel groups double blind
dofetilide vs placebo			
DIAMOND , 2001 n=249/257 follow-up: 24 months	Dofetilide 500 mcg/d5 versus placebo	Persistent AF in patients with heart failure or recent myocardial infarction and reduced LVEF	Parallel groups double blind
SAFIRE-D , 2000 n=182/68 follow-up: 12 months	Dofetilide various doses (250, 500, 1000 mcg/d) versus placebo	Persistent AF or AF1 lasting 2 weeks to 6 months	Parallel groups double blind
sotalol vs placebo			
Bellandi (sotalol vs placebo) , 2001 n=106/92 follow-up: 12 months	sotalol 240 mg/d versus placebo	patients with paroxysmal recurrent or persistent AF	Parallel groups double blind
Benditt , 1999 n=184/69 follow-up: 12 months	Sotalol various doses (80, 120, 160 mg/d) after cardioversion versus placebo	patients with AF or AF1 documented in the last 3 months	Parallel groups double blind
Carunchio (sotalol vs placebo) , 1995 n=20/26 follow-up: 12 months	sotalol 240 mg/d , versus placebo	patients with recurrent AF with >3 episodes in previous 1 year	Parallel groups open
Kochiadakis (sotalol vs placebo) , 2000 n=NA follow-up: 24 months	sotalol 320 mg/d versus placebo	Any documented symptomatic previous or persistent AF	Parallel groups single
Kochiadakis b (sotalol vs placebo) , 2004 n=85/83 follow-up: 24 months	sotalol 300 mg/d versus placebo	Any documented symptomatic previous or persistent AF	Parallel groups single
PAFAC (sotalol vs placebo) , 2004 n=383/88 follow-up: 12 months	sotalol 320 mg/d , versus placebo	Persistent AF lasting >7 daysil	Parallel groups double blind
SAFE-T (sotalol vs placebo) , 2005 n=261/132 follow-up: 12 months	sotalol 320 mg/d versus placebo	Persistent AF lasting 3 days to 1 year	Parallel groups double blind

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Trial	Treatments	Patients	Trials design and methods
Singh , 1991 n=24/10 follow-up: 6 months	Sotalol 80 - 320 mg/d versus placebo	Persistent AF or AF1 lasting 2 weeks to 1 year	Parallel groups double blind
SOPAT (sotalol vs placebo) , 2004 n=264/251 follow-up: 12 months	sotalol 320 mg/d , versus placebo	Paroxysmal AF documented in the last 1 month@4	Parallel groups double blind
sotalol vs bisoprolol			
Plewan , 2001 n=64/64 follow-up: 8 months	Sotalol 160 mg/d versus bisoprolol 5 mg/d	Persistent AF	Parallel groups open
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
sotalol vs flecainide			
Carunchio (sotalol vs flecainide) , 1995 n=20/20 follow-up: 12 months	sotalol 240 mg/d , , sotalol 240 mg/d , versus	patients with recurrent AF with >3 episodes in previous 1 year	Parallel groups open
sotalol vs propafenone			
Kochiadakis b (sotalol vs propafenome) , 2004 n=85/86 follow-up: 24 months	sotalol 300 mg/d , , sotalol 300 mg/d , versus	Any documented symptomatic previous or persistent AF	Parallel groups single

References

ASAP, 2003:

DIAMOND, 2001:

SAFIRE-D, 2000:

Bellandi (sotalol vs placebo), 2001:

Benditt, 1999:

Carunchio (sotalol vs placebo), 1995:

Kochiadakis (sotalol vs placebo), 2000:

Kochiadakis b (sotalol vs placebo), 2004:

PAFAC (sotalol vs placebo), 2004:

SAFE-T (sotalol vs placebo), 2005:
 Singh, 1991:
 SOPAT (sotalol vs placebo), 2004:
 Plewan, 2001:
 AFFIRM Substudy (amiodarone vs class I drugs), 2003:
 AFFIRM Substudy (sotalol vs class I drugs), 2003:
 Carunchio (sotalol vs flecainide), 1995:
 Kochiadakis b (sotalol vs propafenone), 2004:

6 omega-3 polyunsaturated fatty acids

Trial	Treatments	Patients	Trials design and methods
n-3 PUFA vs placebo			
P-OM3 (Kowey) , 2010 n=663 follow-up:	omega-3 PUFA capsules at 8 g/day for the first seven days followed by 4 g/day for total of 24 weeks versus placebo	outpatients with documented symptomatic paroxysmal or persistent AF without significant structural heart disease and initially in sinus rhythm	Parallel groups double-blind

II

References

P-OM3 (Kowey), 2010:

7 Others class I

Trial	Treatments	Patients	Trials design and methods
aprindine vs placebo			
SMART , 2002 n=47/47 follow-up: 6 months	Aprindine 40 mg/d versus placebo	Symptomatic paroxysmal AF having >1 episode monthly or persistent AF lasting <1 month	Parallel groups double blind
bidisomide vs placebo			
AFIB , 1997 n=734/493 follow-up: 6 months	Bidisomide various doses (400, 800, 1200 mg/d) versus placebo	patients with previous AF documented in the last 2 years	Parallel groups open
pilsicainide vs placebo			
Okishige , 2000 n=52/10 follow-up:	Pilsicainide 150 mg/d/d versus placebo	Persistent AF lasting >6 months	Parallel groups single

References

SMART, 2002:

AFIB, 1997:

Okishige, 2000:

8 About TrialResults-center.org

TrialResults-center is an innovative knowledge database that collects the results of RCTs and provides dynamic interactive systematic reviews and meta-analysis in the field of all major heart and vessels diseases.

The TrialResults-center database provides a unique view of the treatment efficacy based on all data provided directly from clinical trial results, offering a valuable alternative to personal bibliographic search, published meta-analysis, etc. Furthermore, it would allow comparing easily the various concurrent therapeutic for the same clinical condition.

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