

Clinical trials of antiarrhythmic drugs for heart failure in all type of heart failure

TrialResults-center www.trialresultscenter.org

1 amiodarone

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
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 >0.55	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

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, Lazzari 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](#)]

2 dronedarone

Trial	Treatments	Patients	Trials design and methods
dronedarone vs placebo			
ANDROMEDA , 2008 [NCT00543699] n=310/317 follow-up: median 2 months	dronedarone 400mg twice daily versus placebo	patients hospitalized with symptomatic heart failure and severe left ventricular systolic dysfunction	Parallel groups double blind

References

ANDROMEDA, 2008:

Kber L, Torp-Pedersen C, McMurray JJ, Gtzsche O, Lvy S, Crijns H, Amlie J, Carlsen J Increased mortality after dronedarone therapy for severe heart failure. *N Engl J Med* 2008;358:2678-87 [[18565860](#)]

3 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.

Rigorous meta-analysis method is used to populate TrialResults-center: widespread search of published and non published trials, study selection using pre-specified criteria, data extraction using standard form.

TrialResults-center is continually updated on a weekly basis. We continually search all new results (whatever their publication channel) and these news results are immediately added to the database with a maximum of 1 week.

TrialResults-center is non-profit and self-funded.