

Clinical trials of rythm control for atrial fibrillation in all type of patients

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1 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

References

P-OM3 (Kowey), 2010:

Kowey PR, Reiffel JA, Ellenbogen KA, Naccarelli GV, Pratt CM Efficacy and Safety of Prescription Omega-3 Fatty Acids for the Prevention of Recurrent Symptomatic Atrial Fibrillation: A Randomized Controlled Trial. JAMA 2010 Nov 15;: [[21078810](https://pubmed.ncbi.nlm.nih.gov/21078810/)] [10.1001/jama.2010.1735](https://doi.org/10.1001/jama.2010.1735)

2 Rhythm control

Trial	Treatments	Patients	Trials design and methods
electrical cardioversion vs rate control			
Hot cafe , 2004 n=104/101 follow-up: 1.7 y	Cardioverted using internal or external cardioversion and then given prophylactic anti-arrhythmic drugs versus rate control (beta-blockers, digitalis, calcium antagonists or atrioventricular node ablation/modification with or without pacemaker implantation	patients with persistent atrial fibrillation	Parallel groups open
RACE , 2002 n=266/256 follow-up: 2.3 y	Rhythm control: serial cardioversions and antiarrhythmic drugs and oral anticoagulantsio versus Rate control (rate slowing medication and anticoagulation	patients with persistent atrial fibrillation after a previous electrical cardioversionio	Parallel groups open

continued...

Trial	Treatments	Patients	Trials design and methods
STAF , 2003 n=100/100 follow-up: 1.6 y	Direct current cardioversion with drugs to maintain sinus rhythm versus rate control and anticoagulants (or antithrombotics)	patients with persistent atrial fibrillation	Parallel groups open
J-RHYTHM <i>ongoing</i> n=NA	-	-	Parallel groups
pharmacological cardioversion vs rate control			
AFFIRM , 2002 [NCT00000556] n=2033/2027 follow-up: mean 3.5y	rhythm control - the antiarrhythmic drugs used included amiodarone, disopyramide, flecainide, moricizine, procainamide, propafenone, quinidine, sotalol, dofetilide or combinations chosen by the treating physician. cardioversion could be employed if necessary versus necessaryrate control - beta-blockers, calcium-channel blockers, digoxin or combination of these drug.	patients with recurrent atrial fibrillation and who were at least 65 years of age or who had other risk factors for stroke or death	Parallel groups open
PIAF , 2000 n=127/125 follow-up: 12 months	rhythm control - amiodarone (600mg for 3 weeks, 200mg maintenance) for pharmacological cardioversion followed if necessary by electrical cardioversion versus rate control - diltiazem90mg BD/TDS and additional therapy at the discretion of the treating physicianall patients were anticoagulated throughout the study period	patients with with chronic atrial fibrillation	Parallel groups open
AF-CHF , 2002 [NCT00597077] n=682/694 follow-up: 37 months	maintenance of sinus rhythm (rhythm control) versus control of the ventricular rate (rate control)	patients with a left ventricular ejection fraction of 35% or less, symptoms of congestive heart failure, and a history of atrial fibrillation	Parallel groups open

References

Hot cafe, 2004:

Opolski G, Torbicki A, Kosior DA, Szulc M, Wozakowska-Kaplon B, Kolodziej P, Achremczyk P Rate control vs rhythm control in patients with nonvalvular persistent atrial fibrillation: the results of the Polish How to Treat Chronic Atrial Fibrillation (HOT CAFE) Study. *Chest* 2004;126:476-86 [[15302734](#)]

RACE, 2002:

Hagens VE, Ranchor AV, Van Sonderen E, Bosker HA, Kamp O, Tijssen JG, Kingma JH, Crijns HJ, Van Gelder IC Effect of rate or rhythm control on quality of life in persistent atrial fibrillation. Results from the Rate Control Versus Electrical Cardioversion (RACE) Study. *J Am Coll Cardiol* 2004;43:241-7 [[14736444](#)]

Van Gelder IC, Hagens VE, Bosker HA, Kingma JH, Kamp O, Kingma T, Said SA, Darmanata JI, Timmermans AJ, Tijssen JG, Crijns HJ A comparison of rate control and rhythm control in patients with recurrent persistent atrial fibrillation. *N Engl J Med* 2002;347:1834-40 [[12466507](#)]

STAF, 2003:

Carlsson J, Miketic S, Windeler J, Cuneo A, Haun S, Micus S, Walter S, Tebbe U Randomized trial of rate-control versus rhythm-control in persistent atrial fibrillation: the Strategies of Treatment of Atrial Fibrillation (STAF) study. *J Am Coll Cardiol* 2003;41:1690-6 [[12767648](#)]

J-RHYTHM, 0:**AFFIRM, 2002:**

Wyse DG, Waldo AL, DiMarco JP, Domanski MJ, Rosenberg Y, Schron EB, Kellen JC, Greene HL, Mickel MC, Dalquist JE, Corley SD A comparison of rate control and rhythm control in patients with atrial fibrillation. *N Engl J Med* 2002;347:1825-33 [[12466506](#)]

PIAF, 2000:

Hohnloser SH, Kuck KH, Lilienthal J Rhythm or rate control in atrial fibrillation—Pharmacological Intervention in Atrial Fibrillation (PIAF): a randomised trial. *Lancet* 2000;356:1789-94 [[11117910](#)]

AF-CHF, 2002:

Roy D, Talajic M, Nattel S, Wyse DG, Dorian P, Lee KL, Bourassa MG, Arnold JM, Buxton AE, Camm AJ, Connolly SJ, Dubuc M, Ducharme A, Guerra PG, Hohnloser SH, Lambert J, Le Heuzey JY, O'Hara G, Pedersen OD, Rouleau JL, Singh BN, Stevenson LW, Stevenson WG, Rhythm control versus rate control for atrial fibrillation and heart failure. *N Engl J Med* 2008 Jun 19;358:2667-77 [[18565859](#)]

3 About TrialResults-center.org

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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.

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