Clinical trials of spironolactone

TrialResults-center www.trialresultscenter.org

1 heart failure

Trial	Treatments	Patients	Trials design and methods
spironolactone vs control			
Cicoira , 2002 n=54/52 follow-up: 12 months	spironolactone 12.5 to 50 mg/day versus control	patients with chronic heart failure	Parallel groups open
Cicoira , 2004 n=47/46 follow-up: 12 months	spironolactone versus control	chronic heart failure patients	open
Ramires , 2000 n=19/16 follow-up: 20 weeks	spironolactone versus standard medical treatment	patients with systolic dysfunction and NYHA class III CHF secondary to dilated or ischemic cardiomyopathy	Parallel groups open
spironolactone vs placebo			
Agostoni , 2005 n=14/15 follow-up: 6 months	spironolactone 25mg/d versus placebo	stable chronic heart failure patients with reduced influences lung diffusion (DLCO)	Parallel groups open Italy
Barr , 1995 n=28/14 follow-up: 8 weeks	spironolactone 50 to 100 mg/day, titrated to blood pressure and plasma potassium (added to an angiotensin-converting enzyme inhibitor) versus placebo	patients with New York Heart Association II to III congestive heart failure	Parallel groups double blind
Farquharson , 2000 n=10/10 follow-up: 4 weeks	spironolactone 50 mg/d versus placebo	patients with NYHA class II to III chronic heart failure on standard diuretic/ACE inhibitor therapy	double blind
Macdonald , 2004 n=43/43 follow-up: 3 months	spironolactone 12.5-50 mg/d versus placebo	patients with New York Heart Association class I-II congestive heart failure taking optimal treatment (including beta blockers)	Cross over double blind
MacFadyen , 1997 n=21/16 follow-up: 8 weeks	spironolactone (50-100 mg/day) versus placebo	patients with stable chronic heart failure	Parallel groups double blind

continued...

Trial	Treatments	Patients	Trials design and methods
Mottram , 2004 n=30 follow-up: 6 months	spironolactone 25 mg/d versus placebo	hypertensive patients with diastolic heart failure	double blind
RALES , 1998 n=822/841 follow-up: 24 mo	spironolactone (25 to 50 mg daily) versus placebo	patients with severeheart failure	Parallel groups Open World
Tsutamoto , 2001 n=20/17 follow-up: 12 weeks	spironolactone 25 mg daily versus placebo	patients with mild-to-moderate nonischemic congestive heart failure	Parallel groups double blind Japan
Yee , 2001 n=28/28 follow-up: 4 weeks	spironolactone 50mg/d versus placebo	patients with New York Heart Association class II to IV congestive heart failure	double blind
TOPCAT , 2014 [NCT00094302] n=3445 follow-up: 3.3 years	spironolactone (15 to 45 mg daily) versus placebo	patients with heart failure and a preserved left ventricular ejection fraction of 45% or more	Parallel groups double-blind
PIE II *ongoing* [NCT00123955] n=NA follow-up: 9 months	Spironolactone 25mg tablet daily for 9 months versus placebo	elderly patients with isolated diastolic heart failure	Parallel groups double blind
spironolactone+captopril vs captopril			
Han , 1994 n=19/16 follow-up: 4 weeks	captopril plus spironolactone versus captopril alone	patients with refractory CHF and New York Heart Association functional class IV without renal dysfunction, hypotension and hyperkalemia	open China
furosemide + spironolactone vs prenalterol			
Dalhstrom , 1986 n=10/10 follow-up: 12 weeks	intensified treatment with diuretics (furosemide- spironolactone) versus prenalterol 100-200 mg daily in addition to their basal treatment	patients with severe chronic congestive heart failure (CHF) due to ischaemic heart disease treated with digitalis and diuretics	Cross over double blind
spironolactone+furosemide vs spironolactone+butizide			
Mauersberger , 1985 n=22 follow-up:	spironolactone 50mg + furosemide 20 mg versus spironolactone 50mg + butizide 5mg	patients with congestive heart failure	open
spironolactone vs spironolactone			

continued...

Trial	Treatments	Patients	Trials design and methods
Nouvel essai *ongoing* [NCT00125437] n=NA follow-up:	spironolactone larger dose versus spironolactone standard dose	severe congestive heart failure in patients with nonischemic cardiomyopathy	Parallel groups single blind

More details and results :

- diuretics for heart failure in all type of patients at http://www.trialresultscenter.org/go-Q75
- diuretics for heart failure in patients with preserved-LVEF heart failure at http://www.trialresultscenter.org/go-Q236
- diuretics for heart failure in elderly at http://www.trialresultscenter.org/go-Q314
- aldosterone blockade for heart failure in all type of patients at http://www.trialresultscenter.org/go-Q488
- mineralocorticoid receptor antagonists for heart failure in all type of patients at http://www.trialresultscenter.org/go-Q665
- mineralocorticoid receptor antagonists for heart failure in HF pEF at http://www.trialresultscenter.org/go-Q666

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PIE II, :

ongoing trial NCT00123955

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Nouvel essai, :

ongoing trial NCT00125437

2 heart failure with preserved LVEF

Trial	Treatments	Patients	Trials design and methods
spironolactone vs placebo			
TOPCAT , 2014 [NCT00094302] n=3445 follow-up: 3.3 years	spironolactone (15 to 45 mg daily) versus placebo	patients with heart failure and a preserved left ventricular ejection fraction of 45% or more	Parallel groups double-blind

More details and results :

- All mechanism for heart failure with preserved LVEF in all type of patients at http://www.trialresultscenter.org/go-Q237

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TOPCAT, 2014:

Pitt B, Pfeffer MA, Assmann SF, Boineau R, Anand IS, Claggett B, Clausell N, Desai AS, Diaz R, Fleg JL, Gordeev I, Harty B, Heitner JF, Kenwood CT, Lewis EF, O'Meara E, Probstfield JL, Shaburishvili T, Shah SJ, Solomon SD, Sweitzer NK, Yang S, McKinlay SM Spironolactone for heart failure with preserved ejection fraction. N Engl J Med 2014;370:1383-92 [24716680] 10.1056/NEJMoa1313731

Entry terms: Veroshpiron, Verospirone, Spiractin, Spirobeta, Spirogamma, Spirolang, Spirono-Isis, Spirono Isis, Spironone, Spirospare, Verospiron, Aldactone, Aldactone A, Aquareduct, duraspiron, Espironolactona Alter, Espironolactona Mundogen, Flumach, Frumikal, Jenaspiron, Novo-Spiroton, Novo Spiroton, NovoSpiroton, Practon, Spiro L.U.T., spiro von ct,