

Clinical trials of spironolactone

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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 severe heart 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...

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|--------------------------------------------------------------------|----------------------------------------------------------------------|--------------------------------------------------------------------------------|---------------------------------|
| Nouvel essai <i>ongoing</i> [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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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

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