

Clinical trials of Losartan

TrialResults-center www.trialresultscenter.org

1 acute myocardial infarction

Trial	Treatments	Patients	Trials design and methods
Losartan vs Captopril			
OPTIMAAL , 2002 n=2744/2733 follow-up: 2.7 y	Losartan, target dose of 50 mg daily versus Captopril, target dose of 50 mg 3 times daily	patients within 10 days of a confirmed acute myocardial infarction and heart failure during the acute phase or a new Q-wave anterior infarction or reinfarction	Parallel groups Double blind

More details and results :

- angiotensin-receptor blockers for acute myocardial infarction in all type of patients at <http://www.trialresultscenter.org/go-Q253>

References

OPTIMAAL, 2002:

Dickstein K, Kjekshus J Effects of losartan and captopril on mortality and morbidity in high-risk patients after acute myocardial infarction: the OPTIMAAL randomised trial. Optimal Trial in Myocardial Infarction with Angiotensin II Antagonist Losartan. Lancet 2002 Sep 7;360:752-60 [[12241832](#)]

2 hypertension

Trial	Treatments	Patients	Trials design and methods
losartan vs placebo			
RENAAL , 2001 n=751/762 follow-up: 3.4 years	Losartan 50 to 100 mg once daily versus placebo	patients with type 2 diabetes and nephropathy	Parallel groups double-blind
RENAAL , 2001 n=751/762 follow-up: 3.4 y	losartan 50 to 100 mg once daily versus placebo	patients with type 2 diabetes and nephropathy	Parallel groups double-blind America, Europe, Asia
losartan vs atenolol			

continued...

Trial	Treatments	Patients	Trials design and methods
LIFE , 2002 n=4605/4588 follow-up: 4.8 y (mean)	losartan versus atenolol	patients aged 5580 years, with previously treated or untreated hypertension (sitting blood pressure 160/200/95/115 mm Hg) and ECG signs of LVH.	Parallel groups Double blind USA, Europe
LIFE (diabetic subgroup) , 2002 n=586/609 follow-up: 4.7 years	losartan 50mg daily at step 1 versus atenolol 50mg daily at step 1	patients with diabetes (subgroup) , hypertension, and signs of left-ventricular hypertrophy on electrocardiograms	Parallel groups double-blind USA, UK, Nordic countries
Losartan vs Captopril			
ELITE-II , 2000 n=1578/1574 follow-up: 1.5 y	Losartan titrated to 50 mg once daily versus Captopril titrated to 50 mg three times daily	patients aged 60 years or older with New York Heart Association class II-IV heart failure and ejection fraction of 40% or less. Patients	Parallel groups double-blind
OPTIMAAL , 2001 n=2744/2733 follow-up: 2.7 y	losartan (titrated to 50 mg once daily) versus Captopril (titrated to 50 mg three times daily)	patients 50 years of age or older, with confirmed acute myocardial infarction and heart failure during the acute phase or a new Q-wave anterior infarction or reinfarction	Parallel groups NA Europe (7 countries)
ELITE , 1997 n=352/370 follow-up: 65279;1 y	65279;Losartan titrated to 50 mg once daily for 48 weeks versus 65279;Captopril titrated to 50 mg three times daily for 48 weeks	naive patients (aged 65 years or more) with NYHA class II-IV heart failure and ejection fractions of 40% or less	Parallel groups double-blind

More details and results :

- anti hypertensive agents for hypertension in diabetic patients at <http://www.trialresultscenter.org/go-Q10>
- anti hypertensive agents for hypertension in all type of patient at <http://www.trialresultscenter.org/go-Q13>
- angiotensin-receptor blockers for hypertension in all diseases requiring ACEi (HF, CHD, HT,...) at <http://www.trialresultscenter.org/go-Q125>
- anti hypertensive agents for hypertension in patients with additional risk factor at <http://www.trialresultscenter.org/go-Q686>

References

RENAAL, 2001:

Brenner BM, Cooper ME, de Zeeuw D, Keane WF, Mitch WE, Parving HH, Remuzzi G, Snapinn SM, Zhang Z, Shahinfar S Effects of losartan on renal and cardiovascular outcomes in patients with type 2 diabetes and nephropathy. N Engl J Med 2001;345:861-9 [1156518]

RENAAL, 2001:

Brenner BM, Cooper ME, de Zeeuw D, Keane WF, Mitch WE, Parving HH, Remuzzi G, Snapinn SM, Zhang Z, Shahinfar S Effects of losartan on renal and cardiovascular outcomes in patients with type 2 diabetes and nephropathy. N Engl J Med 2001;345:861-9 [11565518]

LIFE, 2002:

Dahlof B, Devereux RB, Kjeldsen SE, Julius S, Beevers G, de Faire U, Fyhrquist F, Ibsen H, Kristiansson K, Lederballe-Pedersen O, Lindholm LH, Nieminen MS, Omvik P, Oparil S, Wedel H Cardiovascular morbidity and mortality in the Losartan Intervention For Endpoint reduction in hypertension study (LIFE): a randomised trial against atenolol. Lancet 2002 Mar 23;359:995-1003 [11937178]

LIFE (diabetic subgroup), 2002:

Lindholm LH, Ibsen H, Dahlf B, Devereux RB, Beevers G, de Faire U, Fyhrquist F, Julius S, Kjeldsen SE, Kristiansson K, Lederballe-Pedersen O, Nieminen MS, Omvik P, Oparil S, Wedel H, Aurup P, Edelman J, Snapinn S Cardiovascular morbidity and mortality in patients with diabetes in the Losartan Intervention For Endpoint reduction in hypertension study (LIFE): a randomised trial against atenolol. Lancet 2002;359:1004-10 [11937179] 10.1016/S0140-6736(02)08090-X

Dahlf B, Devereux RB, Kjeldsen SE, Julius S, Beevers G, de Faire U, Fyhrquist F, Ibsen H, Kristiansson K, Lederballe-Pedersen O, Lindholm LH, Nieminen MS, Omvik P, Oparil S, Wedel H Cardiovascular morbidity and mortality in the Losartan Intervention For Endpoint reduction in hypertension study (LIFE): a randomised trial against atenolol. Lancet 2002;359:995-1003 [11937178] 10.1016/S0140-6736(02)08089-3

ELITE-II, 2000:

Pitt B, Poole-Wilson PA, Segal R, Martinez FA, Dickstein K, Camm AJ, Konstam MA, Riegger G, Klinger GH, Neaton J, Sharma D, Thiyagarajan B Effect of losartan compared with captopril on mortality in patients with symptomatic heart failure: randomised trial—the Losartan Heart Failure Survival Study ELITE II. Lancet 2000;355:1582-7 [10821361]

OPTIMAAL, 2001:

Dickstein K, Kjekshus J Effects of losartan and captopril on mortality and morbidity in high-risk patients after acute myocardial infarction: the OPTIMAAL randomised trial. Optimal Trial in Myocardial Infarction with Angiotensin II Antagonist Losartan. Lancet 2002;360:752-60 [12241832]

ELITE, 1997:

Pitt B, Segal R, Martinez FA, Meurers G, Cowley AJ, Thomas I, Deedwania PC, Ney DE, Snively DB, Chang PI Randomised trial of losartan versus captopril in patients over 65 with heart failure (Evaluation of Losartan in the Elderly Study, ELITE) Lancet 1997;349:747-52 [9074572]

3 heart failure

Trial	Treatments	Patients	Trials design and methods
losartan 150mg vs losartan 50mg			
HEAAL , 2009 [NCT00090259] n=1921/1913 follow-up: 4.7 y (median)	losartan 150mg daily versus losartan 50 mg daily	patients with systolic heart failure who couldn't tolerate ACE inhibitors	Parallel groups double blind 30 countries
losartan vs placebo			

continued...

Trial	Treatments	Patients	Trials design and methods
Losartan Phase III U.S. , 1995 <i>unpublished</i> n=237/114 follow-up: 12 wk	Losartan, 50 mg daily versus Placebo	patients with heart failure who had never received ACE inhibitors or who had discontinued ACE inhibitors	Parallel groups double blind
Losartan Phase III International , 1996 <i>unpublished</i> n=254/131 follow-up: 12 wk	Losartan, 50 mg daily versus Placebo	patients with heart failure who had never received ACE inhibitors or who had discontinued ACE inhibitors	Parallel groups double blind
losartan vs losartan			
NCT00090259 <i>ongoing</i> [NCT00090259] n=3656 follow-up:	Losartan versus Losartan	Patients With Symptomatic Heart Failure Intolerant of ACE Inhibitor	Parallel groups double blind
losartan+ACE inhibitor vs ACE inhibitor only			
Hamroff et al. , 1999 n=16/17 follow-up: 6 mo	Losartan, 50 mg daily (plus ACE inhibitor) versus Placebo (plus ACE inhibitor)	patients with severe congestive heart failure (NYHA III-IV) despite treatment with maximally recommended or tolerated doses of ACE inhibitors	Parallel groups double blind
losartan vs captopril			
ELITE , 1997 n=352/370 follow-up: 48 wk	Losartan titrated to 50 mg once daily versus Captopril,titratedto 50 mg three times daily	ACE inhibitor naive patients (aged 65 years or more) with New York Heart Association (NYHA) class IIIIV heart failure and ejection fractions of 40% or less	Parallel groups Double blind United States, Europe and South America
ELITE II , 2000 n=1578/1574 follow-up: median 1.5y	Losartan, target dose 50 mg daily versus Captopril, target dose 50 mg 3 times daily	patients aged 60 years or older with New York Heart Association class IIIIV heart failure and ejection fraction of 40% or less.	Parallel groups Double blind 46 countries
losartan vs enalapril			
Losartan phase II S , 1996 n=108/58 follow-up: 8 weeks	losartan 50 or 25 mg/d versus enalapril 10mg twice daily	patient with heart failure	Parallel groups double blind
losartan phase II US , 1996 n=78/38 follow-up: 12 weeks	losartan 25 and 50 mg/d versus enalapril 10mg twice daily	patients with heart failure	Parallel groups double blind

continued...

Trial	Treatments	Patients	Trials design and methods
Dickstein et al. , 1995 n=108/58 follow-up: 8 wk	Losartan, 25 mg, 50mg daily versus Enalapril, 10 mg twice daily	patients with moderate or severe chronic heart failure in New York Heart Association functional class III or IV and an ejection fraction <or = 35%	Parallel groups double blind
Lang et al. , 1997 n=78/38 follow-up: 12 wk	Losartan titrated to 25 mg ou 50 mg daily versus Enalapril, titrated to 10 mg twice daily	patients with congestive heart failure (New York Heart Association functionalclasses II to IV) and left ventricular ejection fraction <= 45% previously treated with stable doses of ACE inhibitors and diureticagents, with or without concurrent digitalis and othervasodilators	Parallel groups Double blind US, Canada

More details and results :

- angiotensin-receptor blockers for heart failure in all type of patients at <http://www.trialresultscenter.org/go-Q65>
- angiotensin-receptor blockers for heart failure in patients previously untreated with ACE inhibitors at <http://www.trialresultscenter.org/go-Q67>
- angiotensin-receptor blockers for heart failure in patients already receiving ACE inhibitor at <http://www.trialresultscenter.org/go-Q68>

References

HEAAL, 2009:

Konstam MA, Poole-Wilson PA, Dickstein K, Drexler H, Justice SJ, Komajda M, Malbecq W, Martinez FA, Neaton JD, Riegger GA, Guptha S Eur J Heart Fail 2008;10:899-906 [18768350]

Konstam MA, Neaton JD, Dickstein K, Drexler H, Komajda M, Martinez FA, Riegger GA, Malbecq W, Smith RD, Guptha S, Poole-Wilson PA Effects of high-dose versus low-dose losartan on clinical outcomes in patients with heart failure (HEAAL study): a randomised, double-blind trial. Lancet 2009 Nov 28;374:1840-8 [19922995] 10.1016/S0140-6736(09)61913-9

Losartan Phase III U.S., 1995:

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Losartan Phase III International, 1996:

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Sharma D, Buyse M, Pitt B, Rucinska EJ Meta-analysis of observed mortality data from all-controlled, double-blind, multiple-dose studies of losartan in heart failure. Losartan Heart Failure Mortality Meta-analysis Study Group. Am J Cardiol 2000 Jan 15;85:187-92 [10955375]

Sharma D, Buyse M, Pitt B, Rucinska EJ Meta-analysis of observed mortality data from all-controlled, double-blind, multiple-dose studies of losartan in heart failure. Losartan Heart Failure Mortality Meta-analysis Study Group. Am J Cardiol 2000;85:187-92 [10955375]

NCT00090259, :

ongoing trial NCT00090259

Hamroff et al., 1999:

Hamroff G, Katz SD, Mancini D, Blaufarb I, Bijou R, Patel R, Jondeau G, Olivari MT, Thomas S, Le Jemtel TH Addition of angiotensin II receptor blockade to maximal angiotensin-converting enzyme inhibition improves exercise capacity in patients with severe congestive heart failure. Circulation 1999 Mar 2;99:990-2 [10051289]

ELITE, 1997:

Pitt B, Segal R, Martinez FA, Meurers G, Cowley AJ, Thomas I, Deedwania PC, Ney DE, Snavely DB, Chang PI Randomised trial of losartan versus captopril in patients over 65 with heart failure (Evaluation of Losartan in the Elderly Study, ELITE) Lancet 1997 Mar 15;349:747-52 [9074572]

Pitt B, Segal R, Martinez FA, Meurers G, Cowley AJ, Thomas I, Deedwania PC, Ney DE, Snavely DB, Chang PI Randomised trial of losartan versus captopril in patients over 65 with heart failure (Evaluation of Losartan in the Elderly Study, ELITE) Lancet 1997 Mar 15;349:747-52 [9074572]

ELITE II, 2000:

Pitt B, Segal R, Martinez FA, Meurers G, Cowley AJ, Thomas I, Deedwania PC, Ney DE, Snavely DB, Chang PI Randomised trial of losartan versus captopril in patients over 65 with heart failure (Evaluation of Losartan in the Elderly Study, ELITE) Lancet 1997 Mar 15;349:747-52 [9074572]

Losartan phase II S, 1996:

Sharma D, Buyse M, Pitt B, Rucinska EJ Meta-analysis of observed mortality data from all-controlled, double-blind, multiple-dose studies of losartan in heart failure. Losartan Heart Failure Mortality Meta-analysis Study Group. Am J Cardiol 2000 Jan 15;85:187-92 [10955375]

losartan phase II US, 1996:

Sharma D, Buyse M, Pitt B, Rucinska EJ Meta-analysis of observed mortality data from all-controlled, double-blind, multiple-dose studies of losartan in heart failure. Losartan Heart Failure Mortality Meta-analysis Study Group. Am J Cardiol 2000 Jan 15;85:187-92 [10955375]

Dickstein et al., 1995:

Dickstein K, Chang P, Willenheimer R, Haunso S, Remes J, Hall C, Kjekshus J Comparison of the effects of losartan and enalapril on clinical status and exercise performance in patients with moderate or severe chronic heart failure. J Am Coll Cardiol 1995 Aug;26:438-45 [7608448]

Lang et al., 1997:

Lang RM, Elkayam U, Yellen LG, Krauss D, McKelvie RS, Vaughan DE, Ney DE, Makris L, Chang PI Comparative effects of losartan and enalapril on exercise capacity and clinical status in patients with heart failure. The Losartan Pilot Exercise Study Investigators. J Am Coll Cardiol 1997 Oct;30:983-91 [9316528]

4 miscellaneous

Trial	Treatments	Patients	Trials design and methods
losartan vs placebo			
RENAAL , 2001 n=751/762 follow-up: 3.4 years	lLosartan 50 to 100 mg once daily versus placebo	patients with type 2 diabetes and nephropathy	Parallel groups double-blind

continued...

Trial	Treatments	Patients	Trials design and methods
losartan vs atenolol			
LIFE , 2002 n=4605/4588 follow-up: 4.8 y (mean)	losartan versus atenolol	patients aged 5580 years, with previously treated or untreated hypertension (sitting blood pressure 160/200/95/115 mm Hg) and ECG signs of LVH.	Parallel groups Double blind USA, Europe

More details and results :

- angiotensin-receptor blockers for miscellaneous in all type of patients at <http://www.trialresultscenter.org/go-Q425>

References

RENAAL, 2001:

Brenner BM, Cooper ME, de Zeeuw D, Keane WF, Mitch WE, Parving HH, Remuzzi G, Snapinn SM, Zhang Z, Shahinfar S Effects of losartan on renal and cardiovascular outcomes in patients with type 2 diabetes and nephropathy. N Engl J Med 2001;345:861-9 [11565518]

LIFE, 2002:

Dahlof B, Devereux RB, Kjeldsen SE, Julius S, Beevers G, de Faire U, Fyhrquist F, Ibsen H, Kristiansson K, Lederballe-Pedersen O, Lindholm LH, Nieminen MS, Omvik P, Oparil S, Wedel H Cardiovascular morbidity and mortality in the Losartan Intervention For Endpoint reduction in hypertension study (LIFE): a randomised trial against atenolol. Lancet 2002 Mar 23;359:995-1003 [11937178]

5 atrial fibrillation

Trial	Treatments	Patients	Trials design and methods
losartan vs atenolol			
LIFE (AF ancillary study) , 2005 n=4298/4182 follow-up: 4.8 y	losartan versus atenolol	hypertension	

More details and results :

- prevention for atrial fibrillation in patients without history of AF (primary prevention) at <http://www.trialresultscenter.org/go-Q331>

References

LIFE (AF ancillary study), 2005:

Wachtell K, Lehto M, Gerds E, Olsen MH, Hornestam B, Dahlf B, Ibsen H, Julius S, Kjeldsen SE, Lindholm LH, Nieminen MS, Devereux RB Angiotensin II receptor blockade reduces new-onset atrial fibrillation and subsequent stroke compared to atenolol: the Losartan Intervention For End Point Reduction in Hypertension (LIFE) study. J Am Coll Cardiol 2005;45:712-9 [15734615] [10.1016/j.jacc.2004.10.068](https://doi.org/10.1016/j.jacc.2004.10.068)

6 diabetes type 2

Trial	Treatments	Patients	Trials design and methods
losartan vs placebo			
RENAAL , 2001 n=751/762 follow-up: 3.4 y	losartan 50 to 100 mg once daily versus placebo	patients with type 2 diabetes and nephropathy	Parallel groups double-blind America, Europe, Asia
losartan vs atenolol			
LIFE (diabetic subgroup) , 2002 n=586/609 follow-up: 4.7 years	losartan 50mg daily at step 1 versus atenolol 50mg daily at step 1	patients with diabetes (subgroup) , hypertension, and signs of left-ventricular hypertrophy on electrocardiograms	Parallel groups double-blind USA, UK, Nordic countries

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More details and results :

- anti hypertensive agents for diabetes type 2 in patients with hypertension at <http://www.trialresultscenter.org/go-Q83>
- anti hypertensive agents for diabetes type 2 in patients with or without hypertension at <http://www.trialresultscenter.org/go-Q414>
- angiotensin-receptor blockers for diabetes type 2 in all type of patients at <http://www.trialresultscenter.org/go-Q427>
- angiotensin renin system blockade for diabetes type 2 in all type of patients at <http://www.trialresultscenter.org/go-Q438>

References

RENAAL, 2001:

Brenner BM, Cooper ME, de Zeeuw D, Keane WF, Mitch WE, Parving HH, Remuzzi G, Snapinn SM, Zhang Z, Shahinfar S Effects of losartan on renal and cardiovascular outcomes in patients with type 2 diabetes and nephropathy. N Engl J Med 2001;345:861-9 [11565518]

LIFE (diabetic subgroup), 2002:

Lindholm LH, Ibsen H, Dahlf B, Devereux RB, Beevers G, de Faire U, Fyhrquist F, Julius S, Kjeldsen SE, Kristiansson K, Lederballe-Pedersen O, Nieminen MS, Omvik P, Oparil S, Wedel H, Aurup P, Edelman J, Snapinn S Cardiovascular morbidity and mortality in patients with diabetes in the Losartan Intervention For Endpoint reduction in hypertension study (LIFE): a randomised trial against atenolol. Lancet 2002;359:1004-10 [11937179] [10.1016/S0140-6736\(02\)08090-X](https://doi.org/10.1016/S0140-6736(02)08090-X)

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7 patients at high risk for cardiovascular events

Trial	Treatments	Patients	Trials design and methods
losartan vs placebo			
RENAAL , 2001 n=751/762 follow-up: 3.4 years	Losartan 50 to 100 mg once daily versus placebo	patients with type 2 diabetes and nephropathy	Parallel groups double-blind
losartan vs atenolol			
LIFE , 2002 n=4605/4588 follow-up: 4.8 y (mean)	losartan versus atenolol	patients aged 55-80 years, with previously treated or untreated hypertension (sitting blood pressure 160/200/95/115 mm Hg) and ECG signs of LVH.	Parallel groups Double blind USA, Europe

6

More details and results :

- angiotensin-receptor blockers for patients at high risk for cardiovascular events in all type of patients at <http://www.trialresultscenter.org/go-Q97>

References

RENAAL, 2001:

Brenner BM, Cooper ME, de Zeeuw D, Keane WF, Mitch WE, Parving HH, Remuzzi G, Snapinn SM, Zhang Z, Shahinfar S Effects of losartan on renal and cardiovascular outcomes in patients with type 2 diabetes and nephropathy. N Engl J Med 2001;345:861-9 [11565518]

LIFE, 2002:

Dahlf B, Devereux RB, Kjeldsen SE, Julius S, Beevers G, de Faire U, Fyhrquist F, Ibsen H, Kristiansson K, Lederballe-Pedersen O, Lindholm LH, Nieminen MS, Omvik P, Oparil S, Wedel H Cardiovascular morbidity and mortality in the Losartan Intervention For Endpoint reduction in hypertension study (LIFE): a randomised trial against atenolol. Lancet 2002 Mar 23;359:995-1003 [11937178]

8 diabetic kidney disease

Trial	Treatments	Patients	Trials design and methods
losartan vs placebo			
RENAAL , 2001 n=751/762 follow-up: 3.4 y	losartan 50 to 100 mg once daily versus placebo	patients with type 2 diabetes and nephropathy	Parallel groups double-blind America, Europe, Asia

More details and results :

- All mechanism for diabetic kidney disease in all type of patients at <http://www.trialresultscenter.org/go-Q667>

References

RENAAL, 2001:

Brenner BM, Cooper ME, de Zeeuw D, Keane WF, Mitch WE, Parving HH, Remuzzi G, Snapinn SM, Zhang Z, Shahinfar S Effects of losartan on renal and cardiovascular outcomes in patients with type 2 diabetes and nephropathy. N Engl J Med 2001;345:861-9 [11565518]

Entry terms: losartan, Losartan, Cozaar, MK-954, MK 954, MK954, DuP-753, DuP 753, DuP753, Losartan Potassium, Losartan Monopotasium Salt,