

Clinical trials of amlodipine

TrialResults-center www.trialresultscenter.org

1 stable angina

Trial	Treatments	Patients	Trials design and methods
ranolazine 1000mg + amlodipine vs placebo + amlodipine			
ERICA , 2006 [NCT00091429] n=281/284 follow-up: 6 weeks	ranolazine 1000 mg twice a day for 6 weeks + amlodipine (10 mg/d) versus placebo + amlodipine (10 mg/d)	patients with stable chronic angina already treated with the maximal dose of amlodipine (10mg/d)	Parallel groups double blind Europe, USA, Canada

More details and results :

- anti-anginal drugs for stable angina in all type of patients at <http://www.trialresultscenter.org/go-Q263>

References

ERICA, 2006:

Stone PH, Gratsiansky NA, Blokhin A, Huang IZ, Meng L Antianginal efficacy of ranolazine when added to treatment with amlodipine: the ERICA (Efficacy of Ranolazine in Chronic Angina) trial. J Am Coll Cardiol 2006 Aug 1;48:566-75 [[16875985](#)]

2 hypertension

Trial	Treatments	Patients	Trials design and methods
amlodipine vs placebo			
IDNT (amlodipine vs pbo) , 2001 n=567/569 follow-up: 26	Amlodipine 10mg/d versus placebo	hypertensive patients with nephropathy due to type 2 diabetes	Parallel groups Double blind
IDNT (amlodipine vs PBO) , 2001 n=567/569 follow-up: 2.6 years	Amlodipine 10 mg daily versus placebo	hypertensive patients with nephropathy due to type 2 diabetes	Parallel groups double-blind Worldwide

continued...

Trial	Treatments	Patients	Trials design and methods
Tepel et al , 2008 [NCT00124969] n=123/128 follow-up: 19 montsh median (8-30)	Amlodipine 10 mg/day versus matched placebo	hypertensive haemodialysis patients	double blind
amlodipine vs atenolol			
ASCOT-BPLA , 2005 n=9639/9618 follow-up: 5.5 y	amlodipine510 mg adding perindopril 48 mg as required versus atenolol 50100 mg adding bendroflumethiazide 12525 mg and potassium as required	patients with hypertension who were aged 4079 years and had at least three other cardiovascular risk factors.	Parallel groups open Nordic countries and UK
benazepril + amlodipine vs benazepril + hydrochlorothiazide			
ACCOMPLISH (diabetic subgroup) , 2010 [NCT00170950] n=1432/1410 follow-up: 36 months	benazepril, combined with amlodipine versus benazepril, combined with hydrochlorothiazide	patients with diabetes (subgroup) and hypertension at high risk of cardiovascular and related events	Parallel groups double-blind US, Norway, Denmark, Finland
amlodipine vs chlorthalidone			
ALLHAT (CCB vs diu) , 2002 n=9048/15255 follow-up: 4.9y	Amlodipine 2.5 to 10g/d , Amlodipine 2.5 to 10g/d , Amlodipine 2.5 to 10g/d versus chlorthalidone 12.5 to 25 mg/d	participants aged 55 years or older with hypertension and at least 1 other CHD risk factor	Double aveugle US
ALLHAT (amlodipine vs chlor, diabetic subgroup) , 2002 n=2664/4498 follow-up: 4.9 y	amlodipine versus chlorthalidone	diabetic (subgroup) participants aged 55 years or older with hypertension	Parallel groups double-blind
amlodipine vs fosinopril			
FACET , 1997 n=191/189 follow-up: 3.5 y	amlodipine (long acting) 10 mg daily versus fosinopril 20 mg daily	hypertensive patients with NIDDM	Parallel groups open Italy
amlodipine plus benazepril vs hydrochlorothiazide plus benazepril			

continued...

Trial	Treatments	Patients	Trials design and methods
ACCOMPLISH , 2008 [NCT00170950] n=5744/5762 follow-up: 36 months	benazepril 40mg plus amlodipine 5mg daily versus benazepril 40mg plus hydrochlorothiazide 12.5mg daily	patients with hypertension who were at high risk for cardiovascular events	Parallel groups double blind US, Sweden, Norway, Denmark, Finland
amlodipine vs lisinopril			
ALLHAT (CCB vs ACEI) , 2002 n=9048/9054 follow-up: 4.9y	Amlodipine 2.5 to 10g/d , Amlodipine 2.5 to 10g/d , Amlodipine 2.5 to 10g/d versus lisinopril 10 to 40 mg/d	participants aged 55 years or older with hypertension and at least 1 other CHD risk factor	Parallel groups Double aveugle US
amlodipine vs metoprolol			
AASK (amlodipine vs metoprolol) , 2002 n=217/441 follow-up: 30y	Amlodipine 5-10 mg/d versus metoprolol 50-200 mg/d	African Americans aged 18 to 70 years with hypertensive renal disease (GFR, 20-65 mL/min per 1.73m ²)	US
amlodipine vs ramipril			
AASK (amlodipine vs ramipril) , 2002 n=217/436 follow-up: 30	Amlodipine 5-10 mg/d versus ramipril 2.5-10 mg/d	African Americans aged 18 to 70 years with hypertensive renal disease (GFR, 20-65 mL/min per 1.73m ²)	Factorial plan Double blind US

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>
- anti hypertensive agents for hypertension in nephropathy at <http://www.trialresultscenter.org/go-Q19>
- anti hypertensive agents for hypertension in patients undergoing dialysis at <http://www.trialresultscenter.org/go-Q281>
- anti hypertensive agents for hypertension in patients with additional risk factor at <http://www.trialresultscenter.org/go-Q686>

References

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Lewis EJ, Hunsicker LG, Clarke WR, Berl T, Pohl MA, Lewis JB, Ritz E, Atkins RC, Rohde R, Raz I Renoprotective effect of the angiotensin-receptor antagonist irbesartan in patients with nephropathy due to type 2 diabetes. N Engl J Med 2001;345:851-60 [11565517]

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Lewis EJ, Hunsicker LG, Clarke WR, Berl T, Pohl MA, Lewis JB, Ritz E, Atkins RC, Rohde R, Raz I Renoprotective effect of the angiotensin-receptor antagonist irbesartan in patients with nephropathy due to type 2 diabetes. *N Engl J Med* 2001;345:851-60 [[11565517](#)]

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POHL, MA, CORDONNIER, DJ, SPITALOWITZ, S, et al, FOR THE COLLABORATIVE STUDY GROUP Impact of angiotensin receptor blockade with irbesartan on renal function at different systolic blood pressure (SBP) levels in type 2 diabetic nephropathy. *J Am Soc Nephrol* 2002 13: 650A,

Pohl MA, Blumenthal S, Cordonnier DJ, De Alvaro F, Deferrari G, Eisner G, Esmatjes E, Gilbert RE, Hunsicker LG, de Faria JB, Mangili R, Moore J Jr, Reisin E, Ritz E, Schernthaner G, Spitalowitz S, Tindall H, Rodby RA, Lewis EJ Independent and additive impact of blood pressure control and angiotensin II receptor blockade on renal outcomes in the irbesartan diabetic nephropathy trial: clinical implications and limitations. *J Am Soc Nephrol* 2005;16:3027-37 [[16120823](#)] [10.1681/ASN.2004110919](#)

Tepel et al, 2008:

Tepel M, Hopfenmueller W, Scholze A, Maier A, Zidek W *Nephrol Dial Transplant* 2008;23:3605-12 [[18511605](#)] [10.1093/ndt/gfn304](#)

ASCOT-BPLA, 2005:

Dahlof B, Sever PS, Poulter NR, Wedel H, Beevers DG, Caulfield M, Collins R, Kjeldsen SE, Kristinsson A, McInnes GT, Mehlsen J, Nieminen M, O'Brien E, Ostergren J Prevention of cardiovascular events with an antihypertensive regimen of amlodipine adding perindopril as required versus atenolol adding bendroflumethiazide as required, in the Anglo-Scandinavian Cardiac Outcomes Trial-Blood Pressure Lowering Arm (ASCOT-BPLA): a multicentre randomised controlled trial. *Lancet* 2005 Sep 10-16;366:895-906 [[16154016](#)]

ACCOMPLISH (diabetic subgroup), 2010:

Weber MA, Bakris GL, Jamerson K, Weir M, Kjeldsen SE, Devereux RB, Velazquez EJ, Dahlf B, Kelly RY, Hua TA, Hester A, Pitt B Cardiovascular events during differing hypertension therapies in patients with diabetes. *J Am Coll Cardiol* 2010;56:77-85 [[20620720](#)] [10.1016/j.jacc.2010.02.046](#)

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Jamerson K, Weber MA, Bakris GL, Dahlf B, Pitt B, Shi V, Hester A, Gupte J, Gatlin M, Velazquez EJ Benazepril plus amlodipine or hydrochlorothiazide for hypertension in high-risk patients. N Engl J Med 2008 Dec 4;359:2417-28 [19052124]

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AASK (amlodipine vs metoprolol), 2002:

Wright JT Jr, Bakris G, Greene T, Agodoa LY, Appel LJ, Charleston J, Cheek D, Douglas-Baltimore JG, Gassman J, Glassock R, Hebert L, Jamerson K, Lewis J, Phillips RA, Toto RD, Middleton JP, Rostand SG Effect of blood pressure lowering and antihypertensive drug class on progression of hypertensive kidney disease: results from the AASK trial. JAMA 2002;288:2421-31 [12435255]

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Wright JT Jr, Bakris G, Greene T, Agodoa LY, Appel LJ, Charleston J, Cheek D, Douglas-Baltimore JG, Gassman J, Glassock R, Hebert L, Jamerson K, Lewis J, Phillips RA, Toto RD, Middleton JP, Rostand SG Effect of blood pressure lowering and antihypertensive drug class on progression of hypertensive kidney disease: results from the AASK trial. JAMA 2002;288:2421-31 [12435255]

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3 heart failure

Trial	Treatments	Patients	Trials design and methods
amlodipine vs control			
Packer , 1991 <i>unpublished</i> n=NA follow-up: 2 months	-	CHD multiple cause, NYHA class II-III	Double blind
Smith , 1994 n=NA follow-up: 3 months	-	CHD multiple cause, NYHA class II-III	Double blind
Binkley , 1996 <i>unpublished</i> n=NA follow-up: 3 months	-	CHD multiple cause, NYHA class II-III	Double blind
Udelson , 1996 <i>unpublished</i> n=NA follow-up: 3 months	-	patients with congestive heart failure due to ischaemic heart disease, NYHA class II-III	Double blind
Ghali , 1997 <i>unpublished</i> n=NA follow-up: 3 months	-	CHD multiple cause, NYHA class III-IV	Double blind

continued...

Trial	Treatments	Patients	Trials design and methods
amlodipine vs placebo			
PRAISE , 1996 n=571/582 follow-up: median 13.8 mo (range 6-33 mo)	amlodipine 10 mg once daily versus placebo	patients with severe chronic heart failure and ejection fractions of less than 30 percent appl	Parallel groups Double blind US
PRAISE II , 2000 <i>unpublished</i> n=826/826 follow-up: up to 4 years	Amlodipine versus placebo	heart failure in non ischemic cardiomyopathy	

More details and results :

- calcium channel blockers for heart failure in all type of patients at <http://www.trialresultscenter.org/go-Q70>

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unpublished

Packer M, Nicod P, Khanderia RE Randomized, multicenter, double-blind, placebo-controlled evaluation of amlodipine in patients with mild-to-moderate heart failure (abstr). J Am Coll Cardiol 1991;17:274A.

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Binkley PF, Nunziata E, Hatton PS, Cody RJ. Dose and circadian dependent autonomic response to vasodilation with amlodipine in congestive heart failure (abstr) J Am Coll Cardiol 1996;27:774.

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Udelson JE, DeAbate CA, Vijay N. Effect of amlodipine on exercise tolerance and quality of life in mild to moderate heart failure with systolic dysfunction (abstr). J Am Coll Cardiol 1996;27:774.

Ghali, 1997:

unpublished

Ghali JK, Pressler M, Nye R, Cropp A. Is suppression of the neurohormonal system a prerequisite to improve survival in patients with heart failure and impaired left ventricular systolic function (abstr). Circulation 1997;95:385.

PRAISE, 1996:

Packer M, O'Connor CM, Ghali JK, Pressler ML, Carson PE, Belkin RN, Miller AB, Neuberg GW, Frid D, Wertheimer JH, Cropp AB, DeMets DL Effect of amlodipine on morbidity and mortality in severe chronic heart failure. Prospective Randomized Amlodipine Survival Evaluation Study Group. N Engl J Med 1996 Oct 10;335:1107-14 [8813041]

PRAISE II , 2000:

unpublished

Cabell CH, Trichon BH, Velazquez EJ, Dumesnil JG, Anstrom KJ, Ryan T, Miller AB, Belkin RN, Cropp AB, O'Connor CM, Jollis JG Importance of echocardiography in patients with severe nonischemic heart failure: the second Prospective Randomized Amlodipine Survival Evaluation (PRAISE-2) echocardiographic study. Am Heart J 2004;147:151-7 [14691434]

4 diabetes type 2

Trial	Treatments	Patients	Trials design and methods
amlodipine vs placebo			
IDNT (amlodipine vs PBO) , 2001 n=567/569 follow-up: 2.6 years	Amlodipine 10 mg daily versus placebo	hypertensive patients with nephropathy due to type 2 diabetes	Parallel groups double-blind Worldwide
amlodipine vs atenolol			
ASCOT (subgroup) , 2008 n=2565/2572 follow-up: 5.7y	amlodipine with addition of perindopril as required versus atenolol with addition of thiazide as required	Patients with untreated hypertension or treated hypertension; diabetic subgroup with two additional risk factors	Parallel groups double-blind
benazepril + amlodipine vs benazepril + hydrochlorothiazide			
ACCOMPLISH (diabetic subgroup) , 2010 [NCT00170950] n=1432/1410 follow-up: 36 months	benazepril, combined with amlodipine versus benazepril, combined with hydrochlorothiazide	patients with diabetes (subgroup) and hypertension at high risk of cardiovascular and related events	Parallel groups double-blind US, Norway, Denmark, Finland
amlodipine vs chlorthalidone			
ALLHAT (amlodipine vs chlor, diabetic subgroup) , 2002 n=2664/4498 follow-up: 4.9 y	amlodipine versus chlorthalidone	diabetic (subgroup) participants aged 55 years or older with hypertension	Parallel groups double-blind
amlodipine vs fosinopril			

continued...

Trial	Treatments	Patients	Trials design and methods
FACET , 1997 n=191/189 follow-up: 3.5 y	amlodipine (long acting) 10 mg daily versus fosinopril 20 mg daily	hypertensive patients with NIDDM	Parallel groups open Italy

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>

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IDNT (amlodipine vs PBO), 2001:

Lewis EJ, Hunsicker LG, Clarke WR, Berl T, Pohl MA, Lewis JB, Ritz E, Atkins RC, Rohde R, Raz I Renoprotective effect of the angiotensin-receptor antagonist irbesartan in patients with nephropathy due to type 2 diabetes. *N Engl J Med* 2001;345:851-60 [[11565517](#)]

Hunsicker LG, Atkins RC, Lewis JB, Braden G, de Zeeuw D, DeFerra G, Drury P, Locatelli F, Wiegmann TB, Lewis EJ Impact of irbesartan, blood pressure control, and proteinuria on renal outcomes in the Irbesartan Diabetic Nephropathy Trial. *Kidney Int Suppl* 2004;:S99-101 [[15485429](#)] [10.1111/j.1523-1755.2004.09223.x](#)

POHL, MA, CORDONNIER, DJ, SPITALOWITZ, S, et al, FOR THE COLLABORATIVE STUDY GROUP Impact of angiotensin receptor blockade with irbesartan on renal function at different systolic blood pressure (SBP) levels in type 2 diabetic nephropathy. *J Am Soc Nephrol* 2002 13: 650A,

Pohl MA, Blumenthal S, Cordonnier DJ, De Alvaro F, Deferrari G, Eisner G, Esmatjes E, Gilbert RE, Hunsicker LG, de Faria JB, Mangili R, Moore J Jr, Reisin E, Ritz E, Scherthner G, Spitalowitz S, Tindall H, Rodby RA, Lewis EJ Independent and additive impact of blood pressure control and angiotensin II receptor blockade on renal outcomes in the irbesartan diabetic nephropathy trial: clinical implications and limitations. *J Am Soc Nephrol* 2005;16:3027-37 [[16120823](#)] [10.1681/ASN.2004110919](#)

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Ostergren J, Poulter NR, Sever PS, Dahlf B, Wedel H, Beevers G, Caulfield M, Collins R, Kjeldsen SE, Kristinsson A, McInnes GT, Mehlsen J, Nieminen M, O'Brien E The Anglo-Scandinavian Cardiac Outcomes Trial: blood pressure-lowering limb: effects in patients with type II diabetes. *J Hypertens* 2008;26:2103-11 [[18854748](#)] [10.1097/HJH.0b013e328310e0d9](#)

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ACCOMPLISH (diabetic subgroup), 2010:

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Whelton PK, Barzilay J, Cushman WC, Davis BR, Iiamathi E, Kostis JB, Leenen FH, Louis GT, Margolis KL, Mathis DE, Moloo J, Nwachuku C, Panebianco D, Parish DC, Pressel S, Simmons DL, Thadani U Clinical outcomes in antihypertensive treatment of type 2 diabetes, impaired fasting glucose concentration, and normoglycemia: Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT). Arch Intern Med 2005;165:1401-9 [15983290] 10.1001/archinte.165.12.1401

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Tatti et al. Circulation 1997; 96:I-764 (abstr) [0]

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5 coronary artery disease

Trial	Treatments	Patients	Trials design and methods
ranolazine 1000mg + amlodipine vs placebo + amlodipine			
ERICA , 2006 [NCT00091429] n=281/284 follow-up: 6 weeks	ranolazine 1000 mg twice a day for 6 weeks + amlodipine (10 mg/d) versus placebo + amlodipine (10 mg/d)	patients with stable chronic angina already treated with the maximal dose of amlodipine (10mg/d)	Parallel groups double blind Europe, USA, Canada

More details and results :

- anti-anginal drugs for coronary artery disease in all type of patients at <http://www.trialresultscenter.org/go-Q351>

References

ERICA, 2006:

Stone PH, Gratsiansky NA, Blokhin A, Huang IZ, Meng L Antianginal efficacy of ranolazine when added to treatment with amlodipine: the ERICA (Efficacy of Ranolazine in Chronic Angina) trial. J Am Coll Cardiol 2006 Aug 1;48:566-75 [16875985]

6 percutaneous coronary intervention

Trial	Treatments	Patients	Trials design and methods
amlodipine vs placebo			

continued...

Trial	Treatments	Patients	Trials design and methods
Jorgensen (NICOLE) , 2001 n=236/215 follow-up: 4months	amlodipine (10 mg/day) versus placebo	-	double blind

More details and results :

- restenosis prevention for percutaneous coronary intervention in all type of patients at <http://www.trialresultscenter.org/go-Q318>

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Dens JA, Desmet WJ, Coussement P, De Scheerder IK, Kostopoulos K, Kerdsinchai P, Supanantarook C, Piessens JH Usefulness of Nisoldipine for prevention of restenosis after percutaneous transluminal coronary angioplasty (results of the NICOLE study). Nisoldipine in COronary artery disease in LEuven. Am J Cardiol 2001;87:28-33 [11137829]

7 diabetic kidney disease

Trial	Treatments	Patients	Trials design and methods
amlodipine vs placebo			
IDNT (amlodipine vs PBO) , 2001 n=567/569 follow-up: 2.6 years	Amlodipine 10 mg daily versus placebo	hypertensive patients with nephropathy due to type 2 diabetes	Parallel groups double-blind Worldwide

More details and results :

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

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Lewis EJ, Hunsicker LG, Clarke WR, Berl T, Pohl MA, Lewis JB, Ritz E, Atkins RC, Rohde R, Raz I Renoprotective effect of the angiotensin-receptor antagonist irbesartan in patients with nephropathy due to type 2 diabetes. N Engl J Med 2001;345:851-60 [11565517]

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Pohl MA, Blumenthal S, Cordonnier DJ, De Alvaro F, Deferrari G, Eisner G, Esmatjes E, Gilbert RE, Hunsicker LG, de Faria JB, Mangili R, Moore J Jr, Reisin E, Ritz E, Schernthaner G, Spitalowitz S, Tindall H, Rodby RA, Lewis EJ Independent and additive impact of blood pressure control and angiotensin II receptor blockade on renal outcomes in the irbesartan diabetic nephropathy trial: clinical implications and limitations. J Am Soc Nephrol 2005;16:3027-37 [[16120823](#)] [10.1681/ASN.2004110919](#)

Entry terms: atenolol, bisoprolol, Bisoprolol Hydrochloride, Bisoprolol Methanesulfonate Salt, EMD-33512, EMD 33512, EMD33512, CL-297939, CL 297939, CL297939, Concor, Bisoprolol Fumarate, , ranolazine, renolazine, RS 43285-193, Ranexa, RS 43285, RS-43285,