

# Clinical trials of anti hypertensive agents for hypertension in patients with additional risk factor

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## 1 angiotensin-converting enzyme inhibitors

Trial	Treatments	Patients	Trials design and methods
<b>lisinopril vs amlodipine</b>			
<b>ALLHAT (ACEI vs amlodipine) , 2002</b> n=9054/9048 follow-up: 4.9 y	Lisinopril 10 to 40 mg/d versus amlodipine 2.5 to 10 mg/d	participants aged 55 years or older with hypertension and at least 1 other CHD risk fact	Parallel groups Double blind US

## References

### ALLHAT (ACEI vs amlodipine), 2002:

Major outcomes in high-risk hypertensive patients randomized to angiotensin-converting enzyme inhibitor or calcium channel blocker vs diuretic: The Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT). JAMA 2002;288:2981-97 [[12479763](#)]

Norris K, Bourgoigne J, Gassman J, Hebert L, Middleton J, Phillips RA, Randall O, Rostand S, Sherer S, Toto RD, Wright JT Jr, Wang X, Greene T, Appel LJ, Lewis J Cardiovascular outcomes in the African American Study of Kidney Disease and Hypertension (AASK) Trial. Am J Kidney Dis 2006;48:739-51 [[17059993](#)] [10.1053/j.ajkd.2006.08.004](#)

## 2 angiotensin receptor blocker

Trial	Treatments	Patients	Trials design and methods
<b>candesartan vs amlodipine</b>			
<b>CASE-J , 2008</b> n=2354/2349 follow-up: 3.2 years	candesartan-based regimen versus amlodipine-based regimen	high-risk Japanese hypertensive patients	Parallel groups open (blinded assessment) Japan
<b>valsartan vs amlodipine</b>			
<b>VALUE , 2004</b> [ <a href="#">NCT00129233</a> ] n=7649/7596 follow-up: 4.2 y (mean)	valsartan based regimen versus amlodipine based regimen	patients, aged 50 years or older with treated or untreated hypertension and high risk of cardiac events	Parallel groups Double blind 31 countries
<b>losartan vs atenolol</b>			
<b>LIFE , 2002</b> 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

continued...

Trial	Treatments	Patients	Trials design and methods
<b>olmesartan 40 mg vs olmesartan 20 mg plus a calcium-channel blocker</b>			
<b>OSCAR , 2011</b> [NCT00134160] n=578/586 follow-up:	high-dose olmesartan 40 mg per day versus 20-mg/day olmesartan comined with standard dose of amlodipine or azelnidipine	high-risk elderly Japanese hypertension patients	Parallel groups Japan

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Ogihara T, Nakao K, Fukui T, Fukiyama K, Ueshima K, Oba K, Sato T, Saruta T Effects of candesartan compared with amlodipine in hypertensive patients with high cardiovascular risks: candesartan antihypertensive survival evaluation in Japan trial. Hypertension 2008 Feb;51:393-8 [18172059] [10.1161/HYPERTENSIONAHA.107.098475](#)

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### 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]

### OSCAR, 2011:

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## 3 angiotensin-converting enzyme inhibitors

Trial	Treatments	Patients	Trials design and methods
<b>lisinopril vs diuretics</b>			
<b>ALLHAT (ACEI vs chlorthalidone) , 2002</b> n=9054/15255 follow-up: 49 y	lisinopril 10 to 40 mg/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	Parallel groups Double blind US
<b>various ACEI vs nifedipine</b>			
<b>JMIC-B , 2002</b> n=NA follow-up: 30 y	ACE inhibitor versus nifedipine	HBP+CHD	Parallel groups Open Japan

## References

### ALLHAT (ACEI vs chlorthalidone), 2002:

Major outcomes in high-risk hypertensive patients randomized to angiotensin-converting enzyme inhibitor or calcium channel blocker vs diuretic: The Antihypertensive and

Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT). JAMA 2002;288:2981-97 [12479763]

### JMIC-B, 2002:

Yui Y, Sumiyoshi T, Kodama K. Long-term effects of nifedipine retard vs ACE inhibitors in hypertension with coronary heart disease: final report of JMIC-B Circ J 2002; 66 (suppl): 357

## 4 calcium-channel blockers

Trial	Treatments	Patients	Trials design and methods
<b>amlodipine vs atenolol</b>			
ASCOT-BPLA , 2005 n=9639/9618 follow-up: 5.5 y	amlodipine 510 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
<b>verapamil vs atenolol</b>			
INVEST (Pepine) , 2003 [NCT00133692] n=11267/11309 follow-up: 2.7 y	verapamil sustained release 240mg/d versus atenolol 50mg/d	patients with hypertension and CAD	14 countries
<b>amlodipine vs chlorthalidone</b>			
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
<b>verapamil vs diuretic or beta-blocker</b>			
CONVINCE , 2003 n=8241/8361 follow-up: 3 y	controlled-onset extended release (COER) verapamil 180mg/d versus hydrochlorothiazide 12.5 mg/d or atenolol 50 mg/d (investigator choice prior to randomization)	hypertension with 1 or more additional risk factors for cardiovascular disease	Parallel groups Double blind 15 countries
<b>amlodipine plus benazepril vs hydrochlorothiazide plus benazepril</b>			
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
<b>nifedipine vs hydrochlorothiazide + amiloride</b>			
INSIGHT , 2000 n=3157/3164 follow-up: at least 3 years	nifedipine GITS 30mg/d versus hydrochlorothiazide 25mg/d + amiloride 2.5mg/d	HBP + RF	Parallel groups Double blind

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Trial	Treatments	Patients	Trials design and methods
<b>amlodipine vs lisinopril</b>			
<b>ALLHAT (CCB vs ACEI) , 2002</b> 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

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## 5 direct renin inhibitor

Trial	Treatments	Patients	Trials design and methods
<b>aliskiren vs losartan</b>			
ALLAY , 2009 [NCT00219141] n=154/152 follow-up: 9 months	aliskiren 300 mg versus losartan 100 mg	patients with hypertension, increased ventricular wall thickness, and body mass index >25 kg/m <sup>2</sup>	Parallel groups open

## References

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Solomon SD, Appelbaum E, Manning WJ, Verma A, Berglund T, Lukashevich V, Cherif Papst C, Smith BA, Dahlf B Effect of the direct Renin inhibitor aliskiren, the Angiotensin receptor blocker losartan, or both on left ventricular mass in patients with hypertension and left ventricular hypertrophy. *Circulation* 2009;119:530-7 [[19153265](#)]

## 6 About TrialResults-center.org

TrialResults-center is an innovative knowledge database that collects the results of RCTs and provides dynamic interactive systematic reviews and meta-analysis in the field of all major heart and vessels diseases.

The TrialResults-center database provides a unique view of the treatment efficacy based on all data provided directly from clinical trial results, offering a valuable alternative to personal bibliographic search, published meta-analysis, etc. Furthermore, it would allow comparing easily the various concurrent therapeutic for the same clinical condition.

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.

TrialResults-center is non-profit and self-funded.