

Clinical trials of angiotensin-receptor blockers for miscellaneous in all type of patients

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1 angiotensin receptor blocker

Trial	Treatments	Patients	Trials design and methods
ARBs vs control			
Suzuki , 2008 n=183/183 follow-up:	ARBs (valsartan, candesartan, and losartan) versus no ARBs	patients with diabetes and chronic kidney disease on dialysis	Parallel groups open
candesartan vs control			
Takahashi , 2006 n=43/37 follow-up: 19.4 months	candesartan versus control	patients on chronic haemodialysis in stable condition and with no clinical evidence of cardiac disorders	Parallel groups open
candesartan vs conventional treatment			
E-COST , 2005 n=1053/995 follow-up:	candesartan, 2 to 12 mg daily versus conventional antihypertensive drugs other than angiotensin converting enzyme inhibitors or ARBs	Japanese essential hypertensive subjects (sitting blood pressure 140-180/90-110 mmHg) aged 35-79 years	Parallel groups single-blind Japan
E-COST-R , 2005 n=69/72 follow-up:	candesartan versus conventional treatment	hypertensive subjects 60 to 75 years old with non-diabetic chronic renal insufficiency	Parallel groups open
HIJ-CREATE , 2009 n=1024/1025 follow-up: 4.2 y (median)	angiotensin II receptor blocker-based therapy versus non-angiotensin II receptor blocker-based therapy	patients with angiographically documented coronary artery disease and hypertension	Parallel groups open Japan
candesartan vs placebo			
TROPHY , 2006 [NCT00227318] n=409/400 follow-up: 4y	candesartan during 2y followed by 2y of placebo versus placebo	subjects with repeated measurements of systolic pressure of 130 to 139 mm Hg and diastolic pressure of 89 mm Hg or lower, or systolic pressure of 139 mm Hg or lower and diastolic pressure of 85 to 89 mm Hg	Parallel groups double-blind USA
SCOPE , 2003 n=2477/2460 follow-up: 3.7 y (mean)	candesartan, 816 mg once daily (target 160/90) versus placebo	patients aged 70-89 years, with systolic blood pressure 160-179 mmHg, and/or diastolic blood pressure 90-99 mmHg, and a Mini Mental State Examination (MMSE) test score >24	Parallel groups double-blind 15 countries
irbesartan vs placebo			

continued...

Trial	Treatments	Patients	Trials design and methods
IDNT (irbesartan vs pbo) , 2001 n=579/569 follow-up: 2.6 y	Irbesartan 300mg/d (target 135/85) versus placebo	hypertensive patients with nephropathy due to type 2 diabetes	Parallel groups double-blind worldwide
IRMA 2 , 2001 n=404/207 follow-up: 2 years	irbesartan 150 mg daily or 300 mg daily versus placebo	hypertensive patients with type 2 diabetes and microalbuminuria	Parallel groups double-blind multinational
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
olmesartan vs placebo			
ROADMAP , 2010 [NCT00185159] n=2232/2215 follow-up: 3.2 y	olmesartan at 40 mg/day versus placebo	patients with diabetes and at least one additional cardiovascular risk factor, but no evidence of renal dysfunction	Parallel groups double-blind Europe (19 countries)
ORIENT [NCT00141453] n=282/284 follow-up:	olmesartan versus placebo	patients with diabetic Nephropathy and overt proteinuria secondary to type 2 diabetes mellitus	Parallel groups double-blind Japan, Hong Kong
telmisartan vs placebo			
TRANSCEND , 2008 [NCT00153101] n=2954/2972 follow-up: median 56 months (IQR 51-64)	telmisartan 80 mg/day versus placebo	high-risk patients intolerant to angiotensin-converting enzyme inhibitors	Parallel groups double blind 40 countries
PROPHESSE , 2008 [NCT00153062] n=10146/10186 follow-up: 2.5 y	telmisartan 80 mg daily versus placebo	patients who recently had an ischemic stroke	Factorial plan double blind 35 countries
candesartan vs amlodipine			
CASE-J , 2008 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
irbesartan vs amlodipine			
IDNT (irbesartan vs amlodipine) , 2001 n=579/567 follow-up: 26y	Irbesartan 300mg/d (with a target of 135/85) versus amlodipine 10mg/d (with a target of 135/85)	hypertensive patients with nephropathy due to type 2 diabetes	Parallel groups double-blind worldwide
valsartan vs amlodipine			

continued...

Trial	Treatments	Patients	Trials design and methods
VALUE , 2004 [NCT00129233] 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
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
telmisartan vs enalapril			
DETAIL , 2004 n=120/130 follow-up: 5 year	telmisartan 80 mg daily versus enalapril 20 mg daily	subjects with type 2 diabetes and early nephropathy	Parallel groups double-blind
candesartan vs hydrochlorothiazide			
ALPINE , 2003 n=197/196 follow-up: 1 year	candesartan versus hydrochlorothiazide	newly detected hypertensives	Parallel groups double-blind Sweden
olmesartan 40 mg vs olmesartan 20 mg plus a calcium-channel blocker			
OSCAR , 2011 [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
telmisartan vs ramipril			
ONTARGET (telmisartan alone) , 2008 [NCT00153101] n=8542/8576 follow-up: 4.7y	telmisartan 80mg daily versus ramipril 10 mg daily	patients patients with coronary, peripheral, or cerebrovascular disease or diabetes with end-organ damage	Parallel groups double blind 40 countries
telmisartan + ramipril vs ramipril			
ONTARGET (association vs ramipril) , 2008 [NCT00153101] n=8502/8576 follow-up: 4.7y	telmisartan 80mg + ramipril 10mg daily versus ramipril 10 mg daily	patients patients with coronary, peripheral, or cerebrovascular disease or diabetes with end-organ damage	Parallel groups double blind 40 countries
telmisartan + ramipril vs telmisartan			
ONTARGET (association vs telmisartan) , 2008 [NCT00153101] n=8502/8542 follow-up: 4.7y	telmisartan 80mg + ramipril 10mg daily versus telmisartan 80 mg daily	patients patients with coronary, peripheral, or cerebrovascular disease or diabetes with end-organ damage	Parallel groups double blind 40 countries

References

Suzuki, 2008:

Suzuki H, Kanno Y, Sugahara S, Ikeda N, Shoda J, Takenaka T, Inoue T, Araki R Effect of angiotensin receptor blockers on cardiovascular events in patients undergoing hemodialysis:

an open-label randomized controlled trial. *Am J Kidney Dis* 2008;52:501-6 [18653268] [10.1053/j.ajkd.2008.04.031](https://doi.org/10.1053/j.ajkd.2008.04.031)

Takahashi, 2006:

Takahashi A, Takase H, Toriyama T, Sugiura T, Kurita Y, Ueda R, Dohi Y Candesartan, an angiotensin II type-1 receptor blocker, reduces cardiovascular events in patients on chronic haemodialysis—a randomized study. *Nephrol Dial Transplant* 2006;21:2507-12 [16766543] [10.1093/ndt/gfl293](https://doi.org/10.1093/ndt/gfl293)

E-COST, 2005:

Suzuki H, Kanno Y Effects of candesartan on cardiovascular outcomes in Japanese hypertensive patients. *Hypertens Res* 2005;28:307-14 [16138560] [10.1291/hypres.28.307](https://doi.org/10.1291/hypres.28.307)

E-COST-R, 2005:

Nakamura T, Kanno Y, Takenaka T, Suzuki H An angiotensin receptor blocker reduces the risk of congestive heart failure in elderly hypertensive patients with renal insufficiency. *Hypertens Res* 2005;28:415-23 [16156505] [10.1291/hypres.28.415](https://doi.org/10.1291/hypres.28.415)

HIJ-CREATE, 2009:

Kasanuki H, Hagiwara N, Hosoda S, Sumiyoshi T, Honda T, Haze K, Nagashima M, Yamaguchi J, Origasa H, Urashima M, Ogawa H Angiotensin II receptor blocker-based vs. non-angiotensin II receptor blocker-based therapy in patients with angiographically documented coronary artery disease and hypertension: the Heart Institute of Japan Candesartan Randomized Trial for Evaluation in Coronary Artery Disease (HIJ-CREATE). *Eur Heart J* 2009;30:1203-12 [19346521] [10.1093/eurheartj/ehp101](https://doi.org/10.1093/eurheartj/ehp101)

TROPHY, 2006:

Julius S, Nesbitt SD, Egan BM, Weber MA, Michelson EL, Kaciroti N, Black HR, Grimm RH Jr, Messerli FH, Oparil S, Schork MA Feasibility of treating prehypertension with an angiotensin-receptor blocker. *N Engl J Med* 2006;354:1685-97 [16537662] [10.1056/NEJMoa060838](https://doi.org/10.1056/NEJMoa060838)

SCOPE, 2003:

Saxby BK, Harrington F, Wesnes KA, McKeith IG, Ford GA Candesartan and cognitive decline in older patients with hypertension: a substudy of the SCOPE trial. *Neurology* 2008;70:1858-66 [18458219] [10.1212/01.wnl.0000311447.85948.78](https://doi.org/10.1212/01.wnl.0000311447.85948.78)

Lithell H, Hansson L, Skoog I, Elmfeldt D, Hofman A, Olofsson B, Trenkwalder P, Zanchetti A The Study on Cognition and Prognosis in the Elderly (SCOPE): principal results of a randomized double-blind intervention trial. *J Hypertens* 2003;21:875-86 [12714861] [10.1097/01.hjh.0000059028.82022.89](https://doi.org/10.1097/01.hjh.0000059028.82022.89)

IDNT (irbesartan 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]

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]

IRMA 2, 2001:

Parving HH, Lehnert H, Brchner-Mortensen J, Gomis R, Andersen S, Arner P The effect of irbesartan on the development of diabetic nephropathy in patients with type 2 diabetes. *N Engl J Med* 2001;345:870-8 [11565519] [10.1056/NEJMoa011489](https://doi.org/10.1056/NEJMoa011489)

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]

ROADMAP, 2010:

Ritz E, Viberti GC, Ruilope LM, Rabelink AJ, Izzo JL Jr, Katayama S, Ito S, Mimran A, Menne J, Rump LC, Januszewicz A, Haller H Determinants of urinary albumin excretion within the normal range in patients with type 2 diabetes: the Randomised Olmesartan and Diabetes Microalbuminuria Prevention (ROADMAP) study. *Diabetologia* 2010;53:49-57 [19876613] [10.1007/s00125-009-1577-3](https://doi.org/10.1007/s00125-009-1577-3)

Haller H, Ito S, Izzo JL Jr, Januszewicz A, Katayama S, Menne J, Mimran A, Rabelink TJ, Ritz E, Ruilope LM, Rump LC, Viberti G Olmesartan for the delay or prevention of microalbuminuria in type 2 diabetes. *N Engl J Med* 2011 Mar 10;364:907-17 [21388309]

ORIENT, :

TRANSCEND, 2008:

PROPHESSE, 2008:

Yusuf S, Diener HC, Sacco RL, Cotton D, Ounpuu S, Lawton WA, Palesch Y, Martin RH, Albers GW, Bath P, Bornstein N, Chan BP, Chen ST, Cunha L, Dahlf B, De Keyser J, Donnan GA, Estol C, Gorelick P, Gu V, Hermansson K, Hilbrich L, Kaste M, Lu C, Machnig T, — N Engl J Med 2008;359:1225-37 [[18753639](#)] [10.1056/NEJMoa0804593](#)

CASE-J, 2008:

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](#)

IDNT (irbesartan vs amlodipine), 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](#)]

VALUE, 2004:

Julius S, Kjeldsen SE, Weber M, Brunner HR, Ekman S, Hansson L, Hua T, Laragh J, McInnes GT, Mitchell L, Plat F, Schork A, Smith B, Zanchetti A Outcomes in hypertensive patients at high cardiovascular risk treated with regimens based on valsartan or amlodipine: the VALUE randomised trial. Lancet 2004 Jun 19;363:2022-31 [[15207952](#)]

LIFE, 2002:

Dahlöf 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](#)]

DETAIL, 2004:

Barnett AH, Bain SC, Bouter P, Karlberg B, Madsbad S, Jervell J, Mustonen J Angiotensin-receptor blockade versus converting-enzyme inhibition in type 2 diabetes and nephropathy. N Engl J Med 2004;351:1952-61 [[15516696](#)] [10.1056/NEJMoa042274](#)

ALPINE, 2003:

Lindholm LH, Persson M, Alaupovic P, Carlberg B, Svensson A, Samuelsson O Metabolic outcome during 1 year in newly detected hypertensives: results of the Antihypertensive Treatment and Lipid Profile in a North of Sweden Efficacy Evaluation (ALPINE study). J Hypertens 2003;21:1563-74 [[12872052](#)] [10.1097/01.hjh.0000084723.53355.76](#)

OSCAR, 2011:

Ogawa H, Kim-Mitsuyama S, Jinnouchi T, Matsui K, Arakawa K Rationale, design and patient baseline characteristics of OlmeSartan and calcium antagonists randomized (OSCAR) study: a study comparing the incidence of cardiovascular events between high-dose angiotensin II receptor blocker (ARB) monotherapy and combination therapy of ARB with calcium channel blocker in Japanese elderly high-risk hypertensive patients (ClinicalTrials.gov no. NCT00134160). Hypertens Res 2009;32:575-80 [[19444280](#)] [10.1038/hr.2009.60](#)

ONTARGET (telmisartan alone), 2008:

Yusuf S, Teo KK, Pogue J, Dyal L, Copland I, Schumacher H, Dagenais G, Sleight P, Anderson C Telmisartan, ramipril, or both in patients at high risk for vascular events. N Engl J Med 2008 Apr 10;358:1547-59 [[18378520](#)] [10.1056/NEJMoa0801317](#)

Verdecchia P, Sleight P, Mancia G, Fagard R, Trimarco B, Schmieder RE, Kim JH, Jennings G, Jansky P, Chen JH, Liu L, Gao P, Probstfeld J, Teo K, Yusuf S Effects of telmisartan, ramipril, and their combination on left ventricular hypertrophy in individuals at high vascular risk in the Ongoing Telmisartan Alone and in Combination With Ramipril Global End Point Trial and the Telmisartan Randomized Assessment Study in ACE Intolerant Subjects With Cardiovascular Disease. Circulation 2009;120:1380-9 [[19770395](#)]

ONTARGET (association vs ramipril), 2008:

Yusuf S, Teo KK, Pogue J, Dyal L, Copland I, Schumacher H, Dagenais G, Sleight P, Anderson C Telmisartan, ramipril, or both in patients at high risk for vascular events. N Engl J Med 2008 Apr 10;358:1547-59 [[18378520](#)]

ONTARGET (association vs telmisartan), 2008:

Yusuf S, Teo KK, Pogue J, Dyal L, Copland I, Schumacher H, Dagenais G, Sleight P, Anderson C Telmisartan, ramipril, or both in patients at high risk for vascular events. N Engl J Med 2008 Apr 10;358:1547-59 [[18378520](#)]

2 endopeptidase inhibitors

Trial	Treatments	Patients	Trials design and methods
LCZ696 vs placebo			
Ruilope , 2010 n=NA follow-up: 8 weeks	LCZ696 for 8 weeks versus placebo	patients with mild to moderate hypertension	Parallel groups double blind 18 countries

References

Ruilope, 2010:

Ruilope LM, Dukat A, Bhm M, Lacourcire Y, Gong J, Lefkowitz MP Blood-pressure reduction with LCZ696, a novel dual-acting inhibitor of the angiotensin II receptor and neprilysin: a randomised, double-blind, placebo-controlled, active comparator study. Lancet 2010 Mar 15; [20236700] [10.1016/S0140-6736\(09\)61966-8](https://doi.org/10.1016/S0140-6736(09)61966-8)

3 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.

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