Clinical trials of candesartan

TrialResults-center www.trialresultscenter.org

1 hypertension

Trial	Treatments	Patients	Trials design and methods
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 7089 years, with systolic blood pressure 160 179 mmHg, and/or diastolic blood pressure 9099 mmHg, and a Mini Mental State Examination (MMSE) test score >24	Parallel groups double-blind 15 countries
Candesartan vs usual care			

continued...

Trial	Treatments	Patients	Trials design and methods
HIJ-CREATE , 2009 n=1025/1024 follow-up: up to 60 months	cardesartan adjusted dose for target arterial pressure of <130/85 mmHg versus usual care (non-ARB-based pharmacotherapy including angiotensin-converting enzyme-inhibitors)	hypertension with angiographically documented coronary artery disease (acute or stable)	Parallel groups open japan
Takahashi et al , 2006 n=43/37 follow-up:	Candesartan 4-8mg/day versus Conventional treatment	chronic haemodialysis patients	open
Suzuki et al , 2008 n=180/180 follow-up: 1-5 years	Candesartan 12 mg/day, losartan 100 mg/day, or valsartan 160 mg/day versus Conventional treatment	patients undergoing hemodialysis	open
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
candesartan vs hydrochlorothiazide			
ALPINE , 2003 n=197/196 follow-up: 1 year	candesartan versus hydrochlorothiazide	newly detected hypertensives	Parallel groups double-blind Sweden

More details and results :

- 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
- 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 undergoing dialysis at http://www.trialresultscenter.org/go-Q281
- anti hypertensive agents for hypertension in subjects with pre-hypertension at http://www.trialresultscenter.org/go-Q404
- anti hypertensive agents for hypertension in uncomplicated hypertension at http://www.trialresultscenter.org/go-Q685
- anti hypertensive agents for hypertension in patients with additional risk factor at http://www.trialresultscenter.org/go-Q686
- anti hypertensive agents for hypertension in patients with cardiovascular disease at http://www.trialresultscenter.org/go-Q687

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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

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

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

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

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

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

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

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

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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

2 heart failure

Trial	Treatments	Patients	Trials design and methods
candesartan vs placebo			
ARCH-J , 2003 n=148/144 follow-up: 155 d	Candesartan, 8 mg daily versus Placebo	patients with chronic heart failure who were not receiving ACE inhibitor therapy	Parallel groups double blind
CHARM-Alternative , 2003 n=1013/1015 follow-up: Median, 33.7 mo	candesartan (target dose32 mg once daily) versus Placebo	patients with symptomatic heart failure and left-ventricular ejection fraction 40% or less who were notreceiving ACE inhibitors because of previous intolerance	Parallel groups double blind 26 countries
CHARM preserved , 2003 n=1514/1509 follow-up: 36.6 months	candesartan target dose 32 mg once daily versus placebo	patients with NYHA II-IV heart failure and LVEF higher than 40%	Parallel groups double blind 26 countries
Mitrovic et al. , 2003 n=174/44 follow-up: 12 wk	Candesartan, 2 mg, 4mg, 8mg, 16mg daily versus Placebo	patients with CHF (New York Heart Association class II or III) with impaired left ventricular function (ejection fraction <=40%) and pulmonary capillary wedge pressure >=13 mm Hg	Parallel groups double blind Europe, South Africa
SPICE , 2000 n=179/91 follow-up: 12 wk	Candesartan, 16 mg daily versus Placebo	patients with chronic heart failure and left ventricular ejection fraction less than 35% , and history of discontinuing an ACE inhibitor because of intolerance	Parallel groups double blind
STRETCH , 1999 n=633/211 follow-up: 12 wk	Candesartan, 4 mg, 8mg, 16mg daily versus Placebo	Male and female patients 21 to 80 years of age with mild to moderate symptomatic CHF (NYHA class II or III)	Parallel groups Double blind Germany, Czech Republic, Slovenia.
candesartan+ACE inhibitor vs ACE inhibitor only			
RESOLVD association , 1999 n=332/109 follow-up: 43 wk	Candesartan, 4 mg, 8mg daily, plus enalapril, 10 mg twice daily versus Enalapril, 10 mg twice daily	Patients with New York Heart Association functional class NYHA II, III, or IV CHF, 6-minute walk distance (6MWD) >500 m, and ejection fraction (EF) <0.40	Parallel groups multicenter
CHARM-Added , 2003 n=1276/1272 follow-up: Median, 41 mo	Candesartantarget dose 32 mg once daily versus Placebo	patients with New York Heart Association functional class IIIV CHF and left-ventricular ejection fraction40% or lower, and who were being treated with ACE inhibitors.	Parallel groups double blind 26 countries
candesartan vs enalapril			

continued...

Trial	Treatments	Patients	Trials design and methods
RESOLVD (candesartan alone) , 1999 n=327/109 follow-up: 43 wk	Candesartan, 4 mg, 8mg, 16mg daily versus Enalapril, 10 mg twice daily	Patients with New York Heart Association functional class NYHA II, III, or IV CHF, 6-minute walk distance (6MWD) >500 m, and ejection fraction (EF) <0.40	Parallel groups Double blind US, Canada, Europe, Brazil

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 intolerant to ACE inhibitors at http://www.trialresultscenter.org/go-Q66
- 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
- angiotensin-receptor blockers for heart failure in patients with preserved-LVEF heart failure at http://www.trialresultscenter.org/go-Q233
- inhibition of the renin-angiotensin system (ACEI or ARB) for heart failure in patients with preserved-LVEF heart failure at http://www.trialresultscenter.org/go-Q234

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ARCH-J, 2003:

Matsumori A Efficacy and safety of oral candesartan cilexetil in patients with congestive heart failure. Eur J Heart Fail 2003 Oct;5:669-77 [14607207]

CHARM-Alternative, 2003:

Granger CB, McMurray JJ, Yusuf S, Held P, Michelson EL, Olofsson B, Ostergren J, Pfeffer MA, Swedberg K Effects of candesartan in patients with chronic heart failure and reduced left-ventricular systolic function intolerant to angiotensin-converting-enzyme inhibitors: the CHARM-Alternative trial. Lancet 2003 Sep 6;362:772-6 [13678870]

CHARM preserved, 2003:

Yusuf S, Pfeffer MA, Swedberg K, Granger CB, Held P, McMurray JJ, Michelson EL, Olofsson B, Ostergren J Effects of candesartan in patients with chronic heart failure and preserved left-ventricular ejection fraction: the CHARM-Preserved Trial. Lancet 2003 Sep 6;362:777-81 [13678871]

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CHARM-Added, 2003:

McMurray JJ, Ostergren J, Swedberg K, Granger CB, Held P, Michelson EL, Olofsson B, Yusuf S, Pfeffer MA Effects of candesartan in patients with chronic heart failure and reduced left-ventricular systolic function taking angiotensin-converting-enzyme inhibitors: the CHARM-Added trial. Lancet 2003 Sep 6;362:767-71 [13678869]

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3 miscellaneous

Trial	Treatments	Patients	Trials design and methods
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

continued...

Trial	Treatments	Patients	Trials design and methods
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 7089 years, with systolic blood pressure 160 179 mmHg, and/or diastolic blood pressure 9099 mmHg, and a Mini Mental State Examination (MMSE) test score >24	Parallel groups double-blind 15 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
candesartan vs hydrochlorothiazide			
ALPINE , 2003 n=197/196 follow-up: 1 year	candesartan versus hydrochlorothiazide	newly detected hypertensives	Parallel groups double-blind Sweden

More details and results :

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

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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

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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

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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

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

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

4 atrial fibrillation

Trial	Treatments	Patients	Trials design and methods
candesartan vs placebo			
CAPRAF (Tveit) , 2007 [NCT00130975] n=86/85 follow-up: 6 months	candesartan 8 mg once daily for 3-6 weeks before and candesartan 16 mg once daily for 6 months after electrical cardioversion versus placebo	patients undergoing electrical cardioversion for persistent AF	Parallel groups double blind

continued...

Trial	Treatments	Patients	Trials design and methods
CHARM (AF ancillary study) , 2005 n=3225/3221 follow-up: 3.17 y	candesartan versus placebo	Heart failure	

More details and results :

- prevention for atrial fibrillation in patient with history of atrial fibrillation at http://www.trialresultscenter.org/go-Q328
- prevention for atrial fibrillation in patients without history of AF (primary prevention) at http://www.trialresultscenter.org/go-Q331

References

CAPRAF (Tveit), 2007:

Tveit A, Grundvold I, Olufsen M, Seljeflot I, Abdelnoor M, Arnesen H, Smith P Candesartan in the prevention of relapsing atrial fibrillation. Int J Cardiol 2007;120:85-91 [17113170]

CHARM (AF ancillary study), 2005:

McMurray JJ, Ostergren J, Swedberg K, Granger CB, Held P, Michelson EL, Olofsson B, Yusuf S, Pfeffer MA Effects of candesartan in patients with chronic heart failure and reduced left-ventricular systolic function taking angiotensin-converting-enzyme inhibitors: the CHARM-Added trial. Lancet 2003;362:767-71 [13678869] 10.1016/S0140-6736(03)14283-3

5 diabetes type 2

Trial	Treatments	Patients	Trials design and methods
candesartan vs control			
SCOPE (diabetic subgroup) , 2003 n=313/284 follow-up: 3.7 years	candesartan versus control	sub group of diabetic 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 >or= 24	Parallel groups double-blind 15 countries

More details and results :

- anti hypertensive agents for diabetes type 2 in patients with or without hypertension at http://www.trialresultscenter.org/go-Q414

References

SCOPE (diabetic subgroup), 2003:

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

Trenkwalder P, Elmfeldt D, Hofman A, Lithell H, Olofsson B, Papademetriou V, Skoog I, Zanchetti A The Study on COgnition and Prognosis in the Elderly (SCOPE) - major CV events and stroke in subgroups of patients. Blood Press 2005;14:31-7 [15823945] 10.1080/08037050510008823

6 patients at high risk for cardiovascular events

Trial	Treatments	Patients	Trials design and methods
candesartan vs placebo			
SCOPE , 2003 n=2477/2460 follow-up: 3.7 y (mean)	candesartan, 816 mg once daily (target 160/90) versus placebo	patients aged 7089 years, with systolic blood pressure 160 179 mmHg, and/or diastolic blood pressure 9099 mmHg, and a Mini Mental State Examination (MMSE) test score >24	Parallel groups double-blind 15 countries

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

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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

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

7 heart failure with preserved LVEF

Trial	Treatments	Patients	Trials design and methods
candesartan vs placebo			

continued...

Trial	Treatments	Patients	Trials design and methods
CHARM preserved , 2003 n=1514/1509 follow-up: 36.6 months	candesartan target dose 32 mg once daily versus placebo	patients with NYHA II-IV heart failure and LVEF higher than 40%	Parallel groups double blind 26 countries

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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CHARM preserved, 2003:

Yusuf S, Pfeffer MA, Swedberg K, Granger CB, Held P, McMurray JJ, Michelson EL, Olofsson B, Ostergren J Effects of candesartan in patients with chronic heart failure and preserved left-ventricular ejection fraction: the CHARM-Preserved Trial. Lancet 2003 Sep 6;362:777-81 [13678871]

Entry terms: candesartan cilexetil, TCV 116, TCV-116, Atacand, Blopress, Kenzen, Amias, Parapres, candesartan, CV 11974, CV11974, CV-11974,