Clinical trials of more intensive blood pressure lowering strategie

TrialResults-center www.trialresultscenter.org

1 hypertension

Trial	Treatments	Patients	Trials design and methods
more intensive blood pressure lowering strategie vs less intensive blood pressure lowering strategie			
PAST-BP , 2015 n=NA	-	-	
Wei , 2013 n=NA follow-up: 4 years (mean)	BP <=140/90 mm Hg versus BP <=150/90 mm Hg	Chinese hypertensive patients older than 70 years	Parallel groups China
SPS3 , 2013 [NCT00059306.] n=NA follow-up:	less than 130 mm Hg versus 130-149 mm Hg	patients lived in North America, Latin America, and Spain and had recent, MRI-defined symptomatic lacunar infarctions	Parallel groups open-label
HOMED-BP , 2012 n=NA follow-up: 5.3 years (median)	tight control (<125/<80 mm Hg (TC)) of HBP versus usual control (125-134/80-84 mm Hg (UC))	with an untreated systolic/diastolic HBP of 135-179/85-119 mm Hg	Parallel groups
VANLISH , 2010 n=NA follow-up: 3.07 years (median)	strict blood pressure control (<140 mm Hg) versus moderate blood pressure control (>or =140 mm Hg to <150 mm Hg)	patients aged 70 to 84 years with isolated systolic hypertension (sitting blood pressure 160 to 199 mm Hg)	Parallel groups open-label
JATOS , 2008 n=2212/2206 follow-up:	strict treatment to maintain systolic blood pressure below 140 mmHg versus mild treatment to maintain systolic blood pressure below 160 but at or above 140 mmHg	elderly hypertensive patients with essential hypertension (65-85 years old, with a pretreatment systolic blood pressure of above 160 mmHg)	Parallel groups open-label
UKPDS-HDS , 1998 n=758/390 follow-up: 8.4 years	blood pressure of <150/85 mm Hg (with the use of an angiotensin converting enzyme inhibitor captopril or a beta blocker atenolol as main treatment) versus less tight control aiming at a blood pressure of <180/105 mm Hg	patients with type 2 diabetes	Parallel groups open-label UK

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Trial	Treatments	Patients	Trials design and methods
SPRINT , 2015 [NCT01206062] n=4678/4683 follow-up:	target of 120 mm Hg versus target of 140 mm Hg	high-risk hypertensive adults 50 years of age and older with one additional cardiovascular risk factor or preexisting kidney disease	Parallel groups open
Cardio-Sis , 2009 [NCT00421863] n=558/553 follow-up: 2 years	tighter control of systolic BP with a goal of <130 mm Hg versus usual control, with a goal of <140 mm Hg	nondiabetic patients with hypertension and with SBP of 150 mm Hg or higher confirmed at two different times	Parallel groups open Italy
AASK , 2002 n=540/554 follow-up: (range 3-6.4y)	arterial pressure goal of 92 mm Hg or lower versus usual mean arterial pressure goal of 102 to 107 mm Hg/pj	African-Americans,with diastolic blood pressure higher than 94mmHg and a glomerular filtration rate between 20 and 65 ml/min per 1.73 m2	Parallel groups open USA
ABCD target (H) , 2000 n=237/233 follow-up: 5 year	intensive treatment with a diastolic blood pressure goal of 75 mmHg versus moderate treatment with a diastolic blood pressure goal of 80-89 mmHg	diabetes patients with DBP >=90 mmHg	Parallel groups open
ABCD target (N) , 2002 n=237/243 follow-up:	intensive treatment (diastolic blood pressure decrease of 10 mmHg below baseline DBP) versus moderate treatment (diastolic blood pressure goal of 80-89 mmHg)	diabetes patients with diastolic blood pressure between 80 and 89mmHg	Parallel groups open
HOT , 1994 n=12526/6264 follow-up: 3.8 y	less or equal than 85 mmHg, or less or equal than 80 mmHg versus less or equal than 90 mmHg	patients with diastolic blood pressure between 100 mmHg and 115 mmHg	Factorial plan open 26 countries
REIN-2 , 2005 n=169/169 follow-up: 36 months	intensified (systolic/diastolic <130/80 mm Hg) blood-pressure control versus conventional (diastolic <90 mm Hg) blood-pressure control	patients with non-diabetic proteinuric nephropathies receiving background treatment with the ACE inhibitor ramipril	open
MDRD , 1994 n=840 follow-up: 2.2 y	low target blood pressure (mean arterial pressure <92 mm Hg) versus usual target blood pressure (mean arterial pressure <107 mm Hg)	patients with predominantly nondiabetic kidney disease and a glomerular filtration rate of 13 to 55 mL/min per 1.73 m2	open

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Trial	Treatments	Patients	Trials design and methods
Toto , 1995 n=42/35 follow-up:	strict blood pressure control (DBP 65 to 80 mm Hg) versus usual blood pressure control (DBP 85 to 95 mm Hg)	non-diabetic patients (age 25 to 73) with long-standing hypertension (DBP >or = 95 mm Hg), chronic renal insufficiency (GFR <or = 70 m/min/1.73 m2) and a normal urine sediment	open
ACCORD blood pressure , 2008 [NCT00000620] n=2362/2371 follow-up: 4.7y	intensive therapy, targeting a systolic pressure of less than 120 mm Hg versus standard therapy, targeting a systolic pressure of less than 140 mm Hg	patients with a median glycated hemoglobin level of 8.1% at high risk for cardiovascular events	Factorial plan open USA, Canada
ESH-CHL-SHOT *ongoing* [NCT01563731] n=NA	-	-	

More details and results :

- anti hypertensive agents for hypertension in diabetic patients at http://www.trialresultscenter.org/go-Q10
- intensive blood pressure control for hypertension in all type of patients at http://www.trialresultscenter.org/go-Q336
- intensive blood pressure control for hypertension in diabetic patients at http://www.trialresultscenter.org/go-Q343
- intensive blood pressure control for hypertension in non diabetic patients at http://www.trialresultscenter.org/go-Q344
- intensive blood pressure control for hypertension in patients with chronic kidney disease at http://www.trialresultscenter.org/go-Q495

References

PAST-BP, 2015:

Wei, 2013:

Wei Y, Jin Z, Shen G, Zhao X, Yang W, Zhong Y, Wang J Effects of intensive antihypertensive treatment on Chinese hypertensive patients older than 70 years. J Clin Hypertens (Greenwich) 2013;15:420-7 [23730991] 10.1111/jch.12094

SPS3, 2013:

Benavente OR, Coffey CS, Conwit R, Hart RG, McClure LA, Pearce LA, Pergola PE, Szychowski JM Blood-pressure targets in patients with recent lacunar stroke: the SPS3 randomised trial. Lancet 2013;382:507-15 [23726159] 10.1016/S0140-6736(13)60852-1

HOMED-BP, 2012:

Asayama K, Ohkubo T, Metoki H, Obara T, Inoue R, Kikuya M, Thijs L, Staessen JA, Imai Y Cardiovascular outcomes in the first trial of antihypertensive therapy guided by self-measured home blood pressure. Hypertens Res 2012;35:1102-10 [22895063] 10.1038/hr.2012.125

VANLISH, 2010:

Ogihara T, Saruta T, Rakugi H, Matsuoka H, Shimamoto K, Shimada K, Imai Y, Kikuchi K, Ito S, Eto T, Kimura G, Imaizumi T, Takishita S, Ueshima H Target blood pressure for treatment of isolated systolic hypertension in the elderly: valsartan in elderly isolated systolic hypertension study. Hypertension 2010;56:196-202 [20530299] 10.1161/HYPERTENSIONAHA.109.146035

JATOS, 2008:

Principal results of the Japanese trial to assess optimal systolic blood pressure in elderly hypertensive patients (JATOS). Hypertens Res 2008;31:2115-27 [19139601] 10.1291/hypres.31.2115

UKPDS-HDS, 1998:

Tight blood pressure control and risk of macrovascular and microvascular complications in type 2 diabetes: UKPDS 38. UK Prospective Diabetes Study Group. BMJ 1998;317:703-13 [9732337]

SPRINT, 2015:

A Randomized Trial of Intensive versus Standard Blood-Pressure Control. N Engl J Med 2015 Nov 9;: [26551272] 10.1056/NEJMoa1511939

Cardio-Sis, 2009:

Verdecchia P, Staessen JA, Angeli F, de Simone G, Achilli A, Ganau A, Mureddu G, Pede S, Maggioni AP, Lucci D, Reboldi G Usual versus tight control of systolic blood pressure in non-diabetic patients with hypertension (Cardio-Sis): an open-label randomised trial. Lancet 2009;374:525-33 [19683638]

AASK, 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]

ABCD target (H) , 2000:

Estacio RO, Jeffers BW, Gifford N, Schrier RW Effect of blood pressure control on diabetic microvascular complications in patients with hypertension and type 2 diabetes. Diabetes Care 2000;23 Suppl 2:B54-64 [10860192]

ABCD target (N) , 2002:

Schrier RW, Estacio RO, Esler A, Mehler P Effects of aggressive blood pressure control in normotensive type 2 diabetic patients on albuminuria, retinopathy and strokes. Kidney Int 2002;61:1086-97 [11849464] 10.1046/j.1523-1755.2002.00213.x

HOT, 1994:

Hansson L, Zanchetti A, Carruthers SG, Dahlf B, Elmfeldt D, Julius S, Mnard J, Rahn KH, Wedel H, Westerling S Effects of intensive blood-pressure lowering and low-dose aspirin in patients with hypertension: principal results of the Hypertension Optimal Treatment (HOT) randomised trial. HOT Study Group. Lancet 1998;351:1755-62 [9635947]

Hansson L, Zanchetti A The Hypertension Optimal Treatment (HOT) Study: 24-month data on blood pressure and tolerability. Blood Press 1997;6:313-7 [9360003]

Hansson L, Zanchetti A The Hypertension Optimal Treatment (HOT) Study–patient characteristics: randomization, risk profiles, and early blood pressure results. Blood Press 1994;3:322-7 [7866597]

Zanchetti A, Hansson L, Dahlf B, Elmfeldt D, Kjeldsen S, Kolloch R, Larochelle P, McInnes GT, Mallion JM, Ruilope L, Wedel H Effects of individual risk factors on the incidence of cardiovascular events in the treated hypertensive patients of the Hypertension Optimal Treatment Study. HOT Study Group. J Hypertens 2001;19:1149-59 [11403365]

REIN-2, 2005:

Ruggenenti P, Perna A, Loriga G, Ganeva M, Ene-Iordache B, Turturro M, Lesti M, Perticucci E, Chakarski IN, Leonardis D, Garini G, Sessa A, Basile C, Alpa

M, Scanziani R, Sorba G, Zoccali C, Remuzzi G Blood-pressure control for renoprotection in patients with non-diabetic chronic renal disease (REIN-2): multicentre, randomised controlled trial. Lancet 2005;365:939-46 [15766995] 10.1016/S0140-6736(05)71082-5

Tight blood pressure control and risk of macrovascular and microvascular complications in type 2 diabetes: UKPDS 38. UK Prospective Diabetes Study Group. BMJ 1998;317:703-13 [9732337]

MDRD, 1994:

Klahr S, Levey AS, Beck GJ, Caggiula AW, Hunsicker L, Kusek JW, Striker G The effects of dietary protein restriction and blood-pressure control on the progression of chronic renal disease. Modification of Diet in Renal Disease Study Group. N Engl J Med 1994;330:877-84 [8114857]

Lazarus JM, Bourgoignie JJ, Buckalew VM, Greene T, Levey AS, Milas NC, Paranandi L, Peterson JC, Porush JG, Rauch S, Soucie JM, Stollar C Achievement and safety of a low blood pressure goal in chronic renal disease. The Modification of Diet in Renal Disease Study Group. Hypertension 1997;29:641-50 [9040451]

Peterson JC, Adler S, Burkart JM, Greene T, Hebert LA, Hunsicker LG, King AJ, Klahr S, Massry SG, Seifter JL Blood pressure control, proteinuria, and the progression of renal disease. The Modification of Diet in Renal Disease Study. Ann Intern Med 1995;123:754-62 [7574193]

Sarnak MJ, Greene T, Wang X, Beck G, Kusek JW, Collins AJ, Levey AS The effect of a lower target blood pressure on the progression of kidney disease: long-term follow-up of the modification of diet in renal disease study. Ann Intern Med 2005;142:342-51 [15738453]

Toto, 1995:

Toto RD, Mitchell HC, Smith RD, Lee HC, McIntire D, Pettinger WA "Strict" blood pressure control and progression of renal disease in hypertensive nephrosclerosis. Kidney Int 1995;48:851-9 [7474675]

ACCORD blood pressure, 2008:

Gerstein HC, Miller ME, Byington RP, Goff DC Jr, Bigger JT, Buse JB, Cushman WC, Genuth S, Ismail-Beigi F, Grimm RH Jr, Probstfield JL, Simons-Morton DG, Friedewald WT Effects of intensive glucose lowering in type 2 diabetes. N Engl J Med 2008;358:2545-59 [18539917] 10.1056/NEJMoa0802743

Cushman WC, Grimm RH Jr, Cutler JA, Evans GW, Capes S, Corson MA, Sadler LS, Alderman MH, Peterson K, Bertoni A, Basile JN Rationale and design for the blood pressure intervention of the Action to Control Cardiovascular Risk in Diabetes (ACCORD) trial. Am J Cardiol 2007;99:44i-55i [17599425] 10.1016/j.amjcard.2007.03.005

Effects of Intensive Blood-Pressure Control in Type 2 Diabetes Mellitus. N Engl J Med 2010 Mar 14;: [20228401] 10.1056/NEJMoa1001286

ESH-CHL-SHOT, :

ongoing trial NCT01563731

2 diabetes type 2

Trial	Treatments	Patients	Trials design and methods
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ABCD target (H) , 2000 n=237/233 follow-up: 5 year	intensive treatment with a diastolic blood pressure goal of 75 mmHg versus moderate treatment with a diastolic blood pressure goal of 80-89 mmHg	diabetes patients with DBP >=90 mmHg	Parallel groups open

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ABCD target (N) , 2002 n=237/243 follow-up:	intensive treatment (diastolic blood pressure decrease of 10 mmHg below baseline DBP) versus moderate treatment (diastolic blood pressure goal of 80-89 mmHg)	diabetes patients with diastolic blood pressure between 80 and 89mmHg	Parallel groups open

More details and results :

- anti hypertensive agents for diabetes type 2 in patients with hypertension at http://www.trialresultscenter.org/go-Q83

References

ABCD target (H) , 2000:

Estacio RO, Jeffers BW, Gifford N, Schrier RW Effect of blood pressure control on diabetic microvascular complications in patients with hypertension and type 2 diabetes. Diabetes Care 2000;23 Suppl 2:B54-64 [10860192]

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Entry terms: intensive blood pressure lowering strategies, intensive treatment, tighter control of blood pressure, low target blood pressure, strict blood pressure control, intensified blood-pressure control