Clinical trials of niacin for cardiovascular prevention in all type of patients

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1 niacin

Trial	Treatments	Patients	Trials design and methods
niacin vs control			
VA drugs , 1968 n=77/143 follow-up: 3.2 years	-	-	Parallel groups double blind
niacin vs placebo			
CDP niacin , 1975 n=1119/2789 follow-up: 6.2 years	niacin 3 mg/d versus placebo	Hommes, de 30 64 ans	Parallel groups double blind
niacin vs ezetimibe			
ARBITER 6-HALTS (niacin vs ezetimibe) , 2009 [NCT00397657] n=97/111 follow-up: 14 months	extended-release niacin 1 g/d, titrated to max tolerable dose up to 2 g/d (HDL-focused strategy) versus ezetimibe 10 mg/d (LDL-focused strategy)	patients with known coronary or vascular disease or coronary risk equivalents	Parallel groups open US

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VA drugs, 1968:

Schoch HK. The US Veterans Administration Cardiology drug lipid study: an interim report Adv Exp Med Biol. 1968;4:405-420

CDP niacin, 1975:

, Clofibrate and niacin in coronary heart disease. JAMA 1975; 231:360-81 [1088963]

ARBITER 6-HALTS (niacin vs ezetimibe), 2009:

Taylor AJ, Villines TC, Stanek EJ, Devine PJ, Griffen L, Miller M, Weissman NJ, Turco M Extended-release niacin or ezetimibe and carotid intima-media thickness. N Engl J Med 2009 Nov 26;361:2113-22 [19915217]

Villines TC, Stanek EJ, Devine PJ, Turco M, Miller M, Weissman NJ, Griffen L, Taylor AJ The ARBITER 6-HALTS Trial (Arterial Biology for the Investigation of the Treatment Effects of Reducing Cholesterol 6-HDL and LDL Treatment Strategies in Atherosclerosis) Final Results and the Impact of Medication Adherence, Dose, and Treatment Duration. J Am Coll Cardiol 2010 Apr 8;: [20399059] 10.1016/j.jacc.2010.03.017

2 niacin (on top statin)

Trial	Treatments	Patients	Trials design and methods
niacin vs placebo (on top statin)			

continued...

Trial	Treatments	Patients	Trials design and methods
AIM-HIGH , 2011 [NCT00120289] n=1718/1691 follow-up: 32 months	high-dose, extended-release niacin in gradually increasing doses up to 2000 mg daily (+ simvastatin) versus placebo	patients with a history of cardiovascular disease, high triglycerides, and low levels of HDL cholesterol	Parallel groups double blind US, Canada
HPS 2-Thrive [NCT00461630] n=12838/12835 follow-up: 3.9y (median)	2 g of extended-release niacin and 40 mg of laropiprant versus placebo	patients with vascular disease	Parallel groups double blind UK, Scandinavia, China
Oxford Niaspan Study , 2009 [NCT00232531] n=35/36 follow-up: 1 year	niacin 2g daily (added to statin therapy) versus placebo (statins alone)	patients with low HDL-C (<40 mg/dl) and either a type 2 diabetes with coronary heart disease or a carotid/peripheral atherosclerosis	Parallel groups double blind USA
ARBITER 2 , 2009 n=87/80 follow-up: 1 y	long-acting niacin target dose of 1 g/day (added to statin therapy) versus placebo	patients with known coronary artery disease and well controlled on statin therapy	Parallel groups double blind USA
HATS , 2001 n=73/73 follow-up: 3 y	simvastatin plus niacin versus placebo	patients with coronary disease, low HDL cholesterol levels and normal LDL cholesterol levels	Factorial plan double blind USA, Canada

References

AIM-HIGH, 2011:

Boden WE, Probstfield JL, Anderson T, Chaitman BR, Desvignes-Nickens P, Koprowicz K, McBride R, Teo K, Weintraub W Niacin in patients with low HDL cholesterol levels receiving intensive statin therapy. N Engl J Med 2011;365:2255-67 [22085343] 10.1056/NEJMoa1107579

HPS 2-Thrive, :

Landray MJ, Haynes R, Hopewell JC, Parish S, Aung T, Tomson J, Wallendszus K, Craig M, Jiang L, Collins R, Armitage J Effects of extended-release niacin with laropiprant in high-risk patients. N Engl J Med 2014 Jul 17;371:203-12 [25014686] 10.1056/NEJMoa1300955

Oxford Niaspan Study, 2009:

Lee JM, Robson MD, Yu LM, Shirodaria CC, Cunnington C, Kylintireas I, Digby JE, Bannister T, Handa A, Wiesmann F, Durrington PN, Channon KM, Neubauer S, Choudhury RP Effects of high-dose modified-release nicotinic Acid on atherosclerosis and vascular function a randomized, placebo-controlled, magnetic resonance imaging study. J Am Coll Cardiol 2009;54:1787-94 [19874992]

ARBITER 2, 2009:

Taylor AJ, Sullenberger LE, Lee HJ, Lee JK, Grace KA Arterial Biology for the Investigation of the Treatment Effects of Reducing Cholesterol (ARBITER) 2: a double-blind, placebo-controlled study of extended-release niacin on atherosclerosis progression in secondary prevention patients treated with statins. Circulation 2004;110:3512-7 [15537681]

HATS, 2001:

Brown BG, Zhao XQ, Chait A, Fisher LD, Cheung MC, Morse JS, Dowdy AA, Marino EK, Bolson EL, Alaupovic P, Frohlich J, Albers JJ Simvastatin and niacin, antioxidant vitamins, or the combination for the prevention of coronary disease. N Engl J Med 2001 Nov 29;345:1583-92 [11757504]

3 niacin in association

Trial	Treatments	Patients	Trials design and methods
niacin+colestipol vs control			
UCSF SCOR , 1990 n=72 follow-up: 26 months	Niacin 07.5 g colestipol 1520 g versus Conventional therapy	patients with heterozygous familial hypercholesterolemia	
niacin+colestipol vs placebo			
FATS , 1990 n=48/54 follow-up: 2.5 years	niacin (1 g four times a day) and colestipol (10 g three times a day) versus placebo (or colestipol if the low-density lipoprotein [LDL] cholesterol level was elevated)	men no more than 62 years of age with apolipoprotein B levels greater than or equal to 125 mg per deciliter, documented coronary artery disease, and a family history of vascular disease	Parallel groups double-blind
strategy to increase HDL cholesterol vs placebo			
AFREGS , 2005 n=143 follow-up: 30 months	Niacin 0.253 g gemfibrozil 1.2 g cholestyramine 2 g versus placebo	military retirees younger than 76 years of age with low HDL cholesterol levels and angiographically evident coronary disease	Parallel groups double-blind
niacin+ezetimibe vs simvastatin+ezetimibe			
Guyton , 2008 n=NA follow-up: 24 weeks	Niacin 2 g ezetimibe 10 mg simvastatin 20 mg versus Ezetimibe 10 mg simvastatin 20 mg	patients with type IIa or IIb hyperlipidemia	Parallel groups double-blind

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UCSF SCOR, 1990:

Kane JP, Malloy MJ, Ports TA, Phillips NR, Diehl JC, Havel RJ Regression of coronary atherosclerosis during treatment of familial hypercholesterolemia with combined drug regimens. JAMA 1990;264:3007-12 [2243428]

FATS, 1990:

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AFREGS, 2005:

Whitney EJ, Krasuski RA, Personius BE, Michalek JE, Maranian AM, Kolasa MW, Monick E, Brown BG, Gotto AM Jr A randomized trial of a strategy for increasing high-density lipoprotein cholesterol levels: effects on progression of coronary heart disease and clinical events. Ann Intern Med 2005;142:95-104 [15657157]

Guyton, 2008:

Guyton JR, Brown BG, Fazio S, Polis A, Tomassini JE, Tershakovec AM Lipid-altering efficacy and safety of ezetimibe/simvastatin coadministered with extended-release niacin in patients with type IIa or type IIb hyperlipidemia. J Am Coll Cardiol 2008;51:1564-72 [18420099] 10.1016/j.jacc.2008.03.003

4 other cholesterol lowering drugs

Trial	Treatments	Patients	Trials design and methods
clofibtate+niacin vs placebo			

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Trial	Treatments	Patients	Trials design and methods
Carlson (Stockholm) , 1977 n=279/276 follow-up: 5 years	clofibrate, 1 g twice daily, and nicotinic acid 1 g three times daily versus control	survivors of a myocardial infarction below 70 years of age	Parallel groups open Sweden
colestipol-niacin vs placebo			
CLAS , 1987 n=NA follow-up: 65279;2 years	colestipol + niacin versus placebo	nonsmoking men aged 40 to 59 years with previous coronary bypass surgery	Parallel groups double blind

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CLAS, 1987:

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5 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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