Clinical trials of HDL increasing drugs for cardiovascular prevention in all type of patients

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1 CETP inhibitor

Trial	Treatments	Patients	Trials design and methods
dalcetrapib vs			
NCT01516541 *ongoing* [NCT01516541] n=2220 follow-up:	dalcetrapib 600 mg orally daily versus placebo	patients with stable coronary heart disease (CHD), with CHD risk equivalents or at elevated risk for cardiovascular disease	
NCT01059682 *ongoing* [NCT01059682] n=936 follow-up:	dalcetrapib 600 mg orally once a day versus placebo	subjects undergoing coronary angiography who have coronary artery disease	
anacetrapib vs placebo			
REVEAL HPS-3 TIMI-55 , 2017 [NCT01252953] n=30624 follow-up: median 4 years	anacetrapib 100mg daily versus placebo	high risk patients already taking statins	Parallel groups double-blind
REALIZE , 2015 [NCT01524289] n=204/102 follow-up: 52 weeks	oral anacetrapib 100 mg for 52 weeks versus placebo	patients aged 18-80 years with a genotype-confirmed or clinical diagnosis of heterozygous familial hypercholesterolaemia, on optimum lipid-lowering treatment for at least 6 weeks, and with an LDL-C concentration of 259 mmol/L or higher without cardiovascular disease or 181 mmol/L or higher with cardiovascular disease	Parallel groups double-blind
DEFINE , 2010 [NCT00685776] n=811/812 follow-up:	anacetrapib 100mg fr 18 months versus placebo	patients with coronary heart disease or at high risk for coronary heart disease	Parallel groups double-blind 20 countries
dalcetrapib vs placebo			
dal-VESSEL , 2011 n=NA follow-up: 12 weeks	dalcetrapib 600 mg daily versus placebo	men and women with coronary heart disease or coronary heart disease risk equivalents with HDL-cholesterol levels <50 mg/dL	Parallel groups double-blind
dal-OUTCOMES , 2012 [NCT00658515] n=7938/7933 follow-up: 31 montsh (median)	dalcetrapib 600 mg daily beginning 4 to 12 weeks after an index ACS event versus placebo	patients with recent acute coronary syndrome	Parallel groups double-blind 27 countries

continued...

Trial	Treatments	Patients	Trials design and methods
evacetrapib vs placebo			
ACCELERATE , 2017 [NCT01687998] n=6038/6054 follow-up:	evacetrapib at adose of 130 mg versus placebo	Patients at a High-Risk for Vascular Outcomes who had at least one of the following conditions: an acutecoronary syndrome within the previous 30 to 365 days, cerebrovascular atherosclerotic disease, peripheral vascular arterial disease, or diabetes mellitus with coronaryartery disease	Parallel groups double-blind 37 countries
torcetrapib vs placebo			
RADIANCE 1 , 2007 [NCT00136981] n=450/454 follow-up: 24 months	atorvastatin combined with 60 mg of torcetrapib versus atorvastatin monotherapy	patients with heterozygous familial hypercholesterolemia	Parallel groups open
ILLUMINATE , 2007 [NCT00134264] n=7533/7534 follow-up: 1.52y	torcetrapib 60mg daily plus atorvastatin (at a dose established during the runinperiod) versus atorvastatin alone	patients at highcardiovascular risk	Parallel groups double blind 7 countries
RADIANCE 2 , 2007 n=377/375 follow-up: 24 months	torcetrapib 60mg daily (on top of atorvastatin attitrated dose) versus placebo +atorvastatin attitrated dose	patients with mixed dyslipidaemia	Parallel groups double blind North America and Europe
ILLUSTRATE , 2007 [NCT00134173] n=591/597 follow-up: 24 months	atorvastatin plus 60 mg of torcetrapib daily versus atorvastatin monotherapy	patients with coronary disease	Parallel groups open North America and Europe

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NCT01059682, :

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Effects of Anacetrapib in Patients with Atherosclerotic Vascular Disease. N Engl J Med 2017;: [28847206]

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2 fibrates

Trial	Treatments	Patients	Trials design and methods
bezafibrate vs placebo			
BECAIT , 1996 n=47/45 follow-up: 5.0 years	bezafibrate 200 mg three times daily versus placebo	dyslipidaemic male survivors of myocardial infarction who were younger than 45 years at the time of the event	Parallel groups double blind Sweden
BIP , 2000 n=1548/1542 follow-up: 6.2 y	bezafibrate 400 mg/d versus placebo	patients with a previous myocardial infarction or stable angina, total cholesterol of 180 to 250 mg/dL, HDL-C <or =45 mg/dL, triglycerides <or =300 mg/dL, and low-density lipoprotein cholesterol <or =180 mg/dL	Parallel groups double blind Israel
LEADER , 2002 n=783/785 follow-up: 4.6y	bezafibrate 400 mg daily versus placebo	men with lower extremity arterial disease	Parallel groups double-blind UK
SENDCAP , 1998 n=81/83 follow-up: 3.0 years	bezafibrate 400 mg daily versus placebo	type 2 diabetic subjects without a history of clinical cardiovascular	Parallel groups double blind UK
clofibrate vs placebo			

continued...

Trial	Treatments	Patients	Trials design and methods
Acheson , 1972 n=NA follow-up: 6 years	clofibrate versus placebo	cerebral vascular disease	Parallel groups NA UK
Begg , 1971 n=76/79 follow-up: 3.5 y	clofibrate versus placebo	peripheral arteriopathy	Parallel groups
CDP Clofibrate , 1975 n=1103/2789 follow-up: 6.2 years	clofibrate 1.8 mg/d versus placebo	men, 30-64 y	Parallel groups double blind USA
Cullen , 1974 n=20/20 follow-up: 2 years	clofibrate versus placebo		Parallel groups
Hanefeld , 1991 n=379/382 follow-up: 5 years	clofibric acid 1.6 g/day versus placebo	newly diagnosed middle-aged (30- to 55-yr-old) patients with non-insulin-dependent diabetes mellitus	Parallel groups double-blind Germany
Harrold , 1969 n=30/33 follow-up: 1 years	clofibrate versus placebo	diabetic retinopathy	Parallel groups double-blind
Newcastle , 1971 n=244/253 follow-up: 3.6 y	clofibrate 1.5-2 g daily versus placebo	Hommes et femmes <65 ans	Parallel groups double blind UK
Scottish , 1971 n=350/367 follow-up: 3.4 years	clofibrate 1.6-2 g daily versus placebo	Hommes et femmes, de 40 69 ans	Parallel groups double blind Scotland
VA Neurology Section , 1974 n=268/264 follow-up: 1.8 years	clofibrate versus placebo	treatment of cerebrovascular disease	Parallel groups USA
WHO clofibrate , 1978 n=5331/5296 follow-up: 5.3 years	clofibrate 1.6 g daily versus olive oil	primary prevention, Hommes, de 30 59 ans	Parallel groups double blind Scotland, Hungary, Czech Republic
etofibrate vs placebo			
Emmerich , 2009 n=NA follow-up: 12 months	etofibrate 1g/j versus placebo	patients with type 2 diabetes mellitus and concomitant diabetic retinopathy	Parallel groups double-blind Germany
fenofibrate vs placebo			
DAIS , 2001 n=207/211 follow-up: 3.3 years	fenofibrate 200 mg/day versus placebo	men and women with type 2 diabetes and coronary atherosclerosis	Parallel groups double-blind Canada, Finland, France, Sweden

continued...

Trial	Treatments	Patients	Trials design and methods
FIELD , 2005 [ISRCTN64783481] n=4895/4900 follow-up: 5 years	fenofibrate 200mg/d versus Placebo	participants aged 50-75 years, with type 2 diabetes mellitus, and not taking statin therapy at study entry	Parallel groups double blind Australia, New Zealand, Finland
gemfibrozil vs placebo			
Helsinki (HHS) , 1987 n=2046/2035 follow-up: 5 years	gemfibrozil 1,2 g/d versus placebo	asymptomatic middle-aged men (40 to 55 years of age) with primary dyslipidemia (non-HDL cholesterol greater than or equal to 200 mg per deciliter [5.2 mmol per liter]	Parallel groups double blind Finland
HHS (Frick)(secondary prev subgroup) , 1993 n=311/317 follow-up: 5.0 years	gemfibrozil 600 mg twice daily versus placebo	individuals who exhibited symptoms and signs of possible coronary heart disease	Parallel groups double blind Sweden
LOCAT , 1997 n=197/198 follow-up: 32 months	gemfibrozil 1200 mg/d versus placebo	post-coronary bypass men, who had an HDL cholesterol concentration <or = 1.1 mmol/L and LDL cholesterol <or = 4.5 mmol/L	Parallel groups double blind Germany
VA-HIT , 1999 [NCT00283335] n=1264/1267 follow-up: 5.1 years	gemfibrozil 1.2g daily versus placebo	men with coronary heart disease, an HDL cholesterol level of 40 mg per deciliter (1.0 mmol per liter) or less, and an LDL cholesterol level of 140 mg per deciliter (3.6 mmol per liter) or less	Parallel groups double blind USA
fenofibrate vs placebo (on top simvastatine)			
ACCORD lipid , 2010 [NCT00000620] n=2765/2753 follow-up: 4.7y	fenofibrate on top simvastatin versus placebo (on top simvastatine)	high-risk patients with type 2 diabetes	Factorial plan double-blind United States and Canada

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3 niacin

Trial	Treatments	Patients	Trials design and methods
niacin vs control			

continued...

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

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

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Trial	Treatments	Patients	Trials design and methods
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

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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.

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