

Clinical trials of PCSK9 Inhibitors for cardiovascular prevention in all type of patients

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1 PCSK9 Inhibitor

Trial	Treatments	Patients	Trials design and methods
alirocumab vs			
CHOICE I <i>ongoing</i> [NCT01926782] n=NA	-	-	
CHOICE II <i>ongoing</i> [NCT02023879] n=NA	-	-	
NCT01288469 <i>ongoing</i> [NCT01288469] n=NA	-	-	
evolocumab vs			
Mendel 1 , 2012 [NCT01375777] n=NA follow-up:	-	-	
MENDEL 2 [NCT01763827] n=NA	-	-	
YUKAWA-1 , 2014 n=NA follow-up:	-	-	
alirocumab vs ezetimibe (on top statin)			
ODYSSEY OPTIONS I n=NA follow-up: 24 wk	Alirocumab 75 mg with potential up-titration to 150 mg Q2W versus Ezetimibe 10 mg	high-cardiovascular-risk patients with hypercholesterolemia not adequately controlled with atorvastatin (20 or 40 mg) or rosuvastatin (10 or 20 mg)	
ODYSSEY OPTIONS II n=NA follow-up: 24 wk	Alirocumab 75 mg with potential up-titration to 150 mg Q2W versus Ezetimibe 10 mg	high-cardiovascular-risk patients with hypercholesterolemia not adequately controlled with atorvastatin (20 or 40 mg) or rosuvastatin (10 or 20 mg)	
alirocumab vs ezetimibe alone			
ODYSSEY MONO [NCT01644474] n=NA follow-up: 24 wk	Alirocumab 75 mg Q2W versus Ezetimibe 10 mg	hypercholesterolemic patients at moderate cardiovascular risk not receiving statins or other lipid-lowering therapy	double-blind

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Trial	Treatments	Patients	Trials design and methods
evolocumab vs ezetimibe alone			
GAUSS 2 [NCT01763905] n=102/205 follow-up:	evolocumab 140 mg every two weeks (Q2W) or evolocumab 420 mg once monthly (QM) versus ezetimibe 10 mg	patients with statin intolerance	
bococizumab vs placebo			
SPIRE-1 <i>ongoing</i> [NCT01975376] n=NA follow-up:	Bococizumab versus placebo	high risk subjects who are receiving background lipid lowering therapy and have cholesterol laboratory values of LDL-C \geq 70 mg/dL (1.8 mmol/L) and $<$ 100 mg/dL (2.6 mmol/L) or non-HDL-C \geq 100 mg/dl (2.6 mmol/L) and $<$ 130 mg/dL (3.4 mmol/L).	double-blind
SPIRE-2 <i>ongoing</i> [NCT01975389] n=NA follow-up:	bococizumab versus Placebo	high risk subjects who are receiving background lipid lowering therapy and have cholesterol laboratory values of LDL-C \geq 100 mg/dL (2.6 mmol/L) or non-HDL-C \geq 130 mg/dL (3.4 mmol/L).	double-blind
SPIRE-FH <i>ongoing</i> [NCT01968980] n=NA follow-up:	-	subjects with heterozygous familial hypercholesterolemia receiving highly effective statins	double-blind US
SPIRE-HR <i>ongoing</i> [NCT01968954] n=NA follow-up:	Bococizumab versus Placebo	subjects with high cholesterol receiving highly effective statins	double-blind US
SPIRE-LDL <i>ongoing</i> [NCT01968967] n=NA follow-up:	-	subjects with high cholesterol receiving highly effective statins	double-blind US
SPIRE-LL <i>ongoing</i> [NCT02100514] n=NA follow-up:	-	subjects with hyperlipidemia receiving background statin therapy	double-blind US
SPIRE-SI <i>ongoing</i> [NCT02135029] n=NA follow-up:	Bococizumab versus Placebo	-	double-blind
evolocumab vs placebo			
GAUSS 1 , 2012 [NCT01375764] n=95/32 follow-up:	-	statin-intolerant patients	
alirocumab vs placebo (on top statins)			

continued...

Trial	Treatments	Patients	Trials design and methods
ODYSSEY Alternative [NCT01709513] n=NA follow-up: 65279;24 wk	Alirocumab 75 mg with potential up-titration to 150 mg Q2W versus Ezetimibe 10 mg	statin-intolerant patients	double-blind
ODYSSEY COMBO [NCT01644175] n=NA follow-up: 52 wk	Alirocumab 75 mg with potential up-titration to 150 mg Q2W versus Placebo	high cardiovascular risk patients on maximally tolerated statin therapy	double-blind
ODYSSEY COMBO II [NCT01644188] n=NA follow-up: 104 wk	Alirocumab 75 mg with potential up-titration to 150 mg Q2W versus Ezetimibe 10 mg	high cardiovascular risk patients with inadequately controlled hypercholesterolaemia on maximally tolerated doses of statins	double-blind
ODYSSEY FH 1 [NCT01623115] n=NA follow-up: 78 wk	Alirocumab 75 mg with potential up-titration to 150 mg Q2W versus Placebo	patients with heterozygous familial hypercholesterolemia not adequately controlled with current lipid-lowering therapy	double-blind
ODYSSEY FH 2 [NCT01709500] n=NA follow-up: 78 wk	Alirocumab 75 mg with potential up-titration to 150 mg Q2W versus Placebo	patients with heterozygous familial hypercholesterolemia not adequately controlled with current lipid-lowering therapy	double blind
ODYSSEY HIGH FH [NCT01617655] n=NA follow-up: 5278 wk	Alirocumab 150 mg Q2W versus Placebo	patients with heterozygous familial hypercholesterolemia not adequately controlled with current lipid-lowering therapy	
ODYSSEY Long-Term , 2015 [NCT01507831] n=1553/788 follow-up: 78 wk	alirocumab 150 mg as a 1-ml subcutaneous injection every 2 weeks for 78 weeks. versus placebo	patients at high risk for cardiovascular events who had LDL cholesterol levels of 70 mg per deciliter (1.8 mmol per liter) or more and were receiving treatment with statins at the maximum tolerated dose (the highest dose associated with an acceptable side-effect profile), with or without other lipid-lowering therapy	
ODYSSEY OUTCOMES , 2018 [NCT01663402] n=9462/9462 follow-up: 2.8 yr (median)	Alirocumab (on top intensive or maximum-tolerated statin therapy) versus placebo	Post-ACS patients (1 to 12 months)with elevated levels of atherogenic lipoproteins despite intensive or maximum-tolerated statin therapy	Parallel groups double-blind 57 countries
evolocumab vs placebo (on top statins)			
DESCARTES , 2014 [NCT01516879] n=599/302 follow-up: 52 weeks	evolocumab (420 mg) every 4 weeks versus placebo	-	
FOURIER , 2017 [NCT01764633] n=NA follow-up: 2.2 years	evolocumab (either 140 mg every 2 weeks or 420 mg monthly) versus placebo	patients with atherosclerotic cardiovascular disease and LDL cholesterol levels of 70 mg per deciliter (1.8 mmol per liter) or higher who were receiving statin therapy	Parallel groups double-blind

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Trial	Treatments	Patients	Trials design and methods
LAPLACE 2 , 2014 [NCT01763866] n=1117/558 follow-up:	evolucumab + statin versus placebo + statin	-	
LAPLACE-TIMI 57 [NCT01380730] n=NA follow-up:	subcutaneous injections of AMG 145 70 mg, 105 mg, or 140 mg, versus placebo	-	
RUTHERFORD-1 [NCT01375751] n=111/56 follow-up:	AMG 145 350 mg, AMG 145 420 mg versus placebo	heterozygous familial hypercholesterolemia patients	
RUTHERFORD-2 , 2015 [NCT01763918] n=220/109 follow-up:	subcutaneous evolocumab 140 mg every 2 weeks, evolocumab 420 mg monthly versus placebo	heterozygous familial hypercholesterolaemia	

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SPIRE-HR, 0:

SPIRE-LDL, 0:

SPIRE-LL, 0:

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2 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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