

Clinical trials of alirocumab

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1 cardiovascular prevention

Trial	Treatments	Patients	Trials design and methods
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
alirocumab vs placebo (on top statins)			
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

continued...

Trial	Treatments	Patients	Trials design and methods
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
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	-	-	

More details and results :

- PCSK9 Inhibitors for cardiovascular prevention in all type of patients at <http://www.trialresultscenter.org/go-Q599>
- on top statins for cardiovascular prevention in all type of patients at <http://www.trialresultscenter.org/go-Q722>

References

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CHOICE I , :

ongoing trial NCT01926782

CHOICE II , :

ongoing trial NCT02023879

NCT01288469 , :

ongoing trial NCT01288469

Entry terms: alirocumab, REGN727 monoclonal antibody, monoclonal antibody REGN727, SAR236553, Praluent,