

Clinical trials of evolocumab

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1 cardiovascular prevention

Trial	Treatments	Patients	Trials design and methods
evolocumab vs			
Mendel 1 , 2012 [NCT01375777] n=NA follow-up:	-	-	
MENDEL 2 [NCT01763827] n=NA	-	-	
YUKAWA-1 , 2014 n=NA follow-up:	-	-	
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	
evolocumab vs placebo			
GAUSS 1 , 2012 [NCT01375764] n=95/32 follow-up:	-	statin-intolerant patients	
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

continued...

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 evolucumab 140 mg every 2 weeks, evolucumab 420 mg monthly versus placebo	heterozygous familial hypercholesterolaemia	

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

Mendel 1, 2012:

Koren MJ, Scott R, Kim JB, Knusel B, Liu T, Lei L, Bolognese M, Wasserman SM Efficacy, safety, and tolerability of a monoclonal antibody to proprotein convertase subtilisin/kexin type 9 as monotherapy in patients with hypercholesterolaemia (MENDEL): a randomised, double-blind, placebo-controlled, phase 2 study. *Lancet* 2012 Dec 8;380:1995-2006 [23141812] [10.1016/S0140-6736\(12\)61771-1](https://doi.org/10.1016/S0140-6736(12)61771-1)

MENDEL 2, :

YUKAWA-1, 2014:

Hirayama A, Honarpour N, Yoshida M, Yamashita S, Huang F, Wasserman SM, Teramoto T Effects of evolucumab (AMG 145), a monoclonal antibody to PCSK9, in hypercholesterolemic, statin-treated Japanese patients at high cardiovascular risk—primary results from the phase 2 YUKAWA study. *Circ J* 2014;78:1073-82 [24662398]

GAUSS 2, :

Stroes E, Colquhoun D, Sullivan D, Civeira F, Rosenson RS, Watts GF, Bruckert E, Cho L, Dent R, Knusel B, Xue A, Scott R, Wasserman SM, Rocco M Anti-PCSK9 antibody effectively lowers cholesterol in patients with statin intolerance: the GAUSS-2 randomized, placebo-controlled phase 3 clinical trial of evolucumab. *J Am Coll Cardiol* 2014 Jun 17;63:2541-8 [24694531]

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DESCARTES, 2014:

Blom DJ, Hala T, Bolognese M, Lillestol MJ, Toth PD, Burgess L, Ceska R, Roth E, Koren MJ, Ballantyne CM, Monsalvo ML, Tsirtsonis K, Kim JB, Scott R, Wasserman SM, Stein EA A 52-week placebo-controlled trial of evolocumab in hyperlipidemia. N Engl J Med 2014 May 8;370:1809-19 [24678979]

FOURIER, 2017:

Sabatine MS, Giugliano RP, Keech AC, Honarpour N, Wiviott SD, Murphy SA, Kuder JF, Wang H, Liu T, Wasserman SM, Sever PS, Pedersen TR Evolocumab and Clinical Outcomes in Patients with Cardiovascular Disease. N Engl J Med 2017;376:1713-1722 [28304224]

LAPLACE 2, 2014:

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LAPLACE-TIMI 57, :

Giugliano RP, Desai NR, Kohli P, Rogers WJ, Somaratne R, Huang F, Liu T, Mohanavelu S, Hoffman EB, McDonald ST, Abrahamson TE, Wasserman SM, Scott R, Sabatine MS Efficacy, safety, and tolerability of a monoclonal antibody to proprotein convertase subtilisin/kexin type 9 in combination with a statin in patients with hypercholesterolemia (LAPLACE-TIMI 57): a randomised, placebo-controlled, dose-ranging, phase 2 study. Lancet 2012 Dec 8;380:2007-17 [23141813]

RUTHERFORD-1, :

Raal F, Scott R, Somaratne R, Bridges I, Li G, Wasserman SM, Stein EA Low-density lipoprotein cholesterol-lowering effects of AMG 145, a monoclonal antibody to proprotein convertase subtilisin/kexin type 9 serine protease in patients with heterozygous familial hypercholesterolemia: the Reduction of LDL-C with PCSK9 Inhibition in Heterozygous Familial Hypercholesterolemia Disorder (RUTHERFORD) randomized trial. Circulation 2012 Nov 13;126:2408-17 [23129602]

RUTHERFORD-2, 2015:

Raal FJ, Stein EA, Dufour R, Turner T, Civeira F, Burgess L, Langslet G, Scott R, Olsson AG, Sullivan D, Hovingh GK, Cariou B, Gouni-Berthold I, Somaratne R, Bridges I, Scott R, Wasserman SM, Gaudet D PCSK9 inhibition with evolocumab (AMG 145) in heterozygous familial hypercholesterolemia (RUTHERFORD-2): a randomised, double-blind, placebo-controlled trial. Lancet 2015 Jan 24;385:331-40 [25282519]

Entry terms: AMG 145, evolocumab, AMG-145, Repatha