

SUPPLEMENTAL MATERIAL

Table S1. Search strategy.

Search String	("hydroxymethylglutaryl-coa reductase inhibitors"[Pharmacological Action] OR "hydroxymethylglutaryl-coa reductase inhibitors"[MeSH Terms] OR ("hydroxymethylglutaryl-coa"[All Fields] AND "reductase"[All Fields] AND "inhibitors"[All Fields]) OR "hydroxymethylglutaryl-coa reductase inhibitors"[All Fields] OR "statins"[All Fields]) OR (("proprotein convertases"[MeSH Terms] OR ("proprotein"[All Fields] AND "convertases"[All Fields]) OR "proprotein convertases"[All Fields] OR ("proprotein"[All Fields] AND "convertase"[All Fields]) OR "proprotein convertase"[All Fields]) AND subtilisin/kexin[All Fields] AND type[All Fields] AND 9[All Fields] AND ("antagonists and inhibitors"[Subheading] OR ("antagonists"[All Fields] AND "inhibitors"[All Fields]) OR "antagonists and inhibitors"[All Fields] OR "inhibitors"[All Fields])) OR (pcsk[All Fields] AND 9[All Fields] AND ("antagonists and inhibitors"[Subheading] OR ("antagonists"[All Fields] AND "inhibitors"[All Fields]) OR "antagonists and inhibitors"[All Fields] OR "inhibitors"[All Fields])) OR ("ezetimibe"[MeSH Terms] OR "ezetimibe"[All Fields]) AND ("cholesterol, ldl"[MeSH Terms] OR ("cholesterol"[All Fields] AND "ldl"[All Fields]) OR "ldl cholesterol"[All Fields] OR ("low"[All Fields] AND "density"[All Fields] AND "lipoprotein"[All Fields] AND "cholesterol"[All Fields]) OR "low density lipoprotein cholesterol"[All Fields]) OR ldl-c[All Fields] AND ("diabetes mellitus"[MeSH Terms] OR ("diabetes"[All Fields] AND "mellitus"[All Fields]) OR "diabetes mellitus"[All Fields])
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Table S2. Cochrane Quality risk assessment.

Studies	Randomization	Allocation concealment	Blinding (Physician/Patient)	Adjudication of outcomes	Selective outcome reporting	Incomplete data reporting addressed?	Free of other bias?
Statins							
PMSGCRP (1993) ¹	Low risk	Moderate risk	Low risk	Moderate risk	Low risk	Low risk	Low risk
4S (1994) ²	Low risk	Moderate risk	Low risk	Low risk	Low risk	Low risk	Low risk
WOSCOP (1995) ³	Low risk	Moderate risk	Low risk	Low risk	Low risk	Low risk	Low risk
LIPID (1998) ⁴	Low risk	Moderate risk	Low risk	Low risk	Low risk	Low risk	Low risk
AFCAPS/TexCAPS (1998) ⁵	Low risk	Moderate risk	Low risk	Low risk	Low risk	Low risk	Low risk
GISSI PREV (2000) ⁶	Moderate risk	Moderate risk	High risk	Moderate risk	Low risk	Moderate risk	Moderate risk
ALLHAT-LLT (2002) ⁷	Low risk	Low risk	High risk	Low risk	Low risk	Moderate risk	Moderate risk
GREACE (2002) ⁸	Low risk	Moderate risk	High risk	Low risk	Low risk	Low risk	Low risk
PROSPER (2002) ⁹	Low risk	Low risk	Low risk	Low risk	Low risk	Moderate risk	Low risk
HPS (2003) ¹⁰	Low risk	Moderate risk	Low risk	Low risk	High risk	Low risk	Moderate risk
ASCOT-LLA (2003) ¹¹	Low risk	Moderate risk	Low risk	Moderate risk	Low risk	Low risk	Moderate risk
A to Z (2004) ¹²	Low risk	Moderate risk	Low risk	Low risk	Low risk	Low risk	Low risk
PROVE IT (2004) ¹³	Low risk	Moderate risk	Low risk	Low risk	Low risk	Low risk	Low risk
IDEAL (2005) ¹⁴	Moderate risk	Low risk	High risk	Low risk	Low risk	Low risk	Moderate risk

FOURIER (2017) ³¹	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
ODYSSEY OUTCOMES (2018) ³²	Low risk	Low risk	Low risk	Low risk	Low risk	Moderate risk	Low risk

Table S3. Baseline characteristics of the entire study population for each trial.

Studies (Year)	N	Groups	Age (years)	Men (%)	Coronary heart disease (%)	Hypertension (%)	Smoking (%)
PMSGCRP (1993) ¹	1,062	Pravastatin 20 mg	55	77	32	47	28
		Placebo	55	76	36	48	30
4S (1994) ²	4,444	Simvastatin 20-40 mg	58.6	82	100	26	24
		Placebo	58.6	81	100	26	27
WOSCOPS (1995) ³	6,595	Pravastatin 40 mg	55.3	100	0.0	16	44
		Placebo	55.1	100	0.0	15	44
LIPID (1998) ⁴	9,014	Pravastatin 40 mg	62	83	100	41	9
		Placebo	62	83	100	42	10
AFCAPS/TexCAPS (1998) ⁵	6,605	Lovastatin 20-40 mg	58	85	0.0	22	13
		Placebo	58	85	0.0	22	12
GISSI PREV (2000) ⁶	3,460	Pravastatin 20 mg	59.3	86.3	—	36.5	11.8
		Usual care					
ALLHAT-LLT (2002) ⁷	10,355	Pravastatin 40 mg	66.4	51.4	13.4	89.8	23.1
		Usual care	66.3	51.0	15.0	89.9	23.3
GREACE (2002) ⁸	1,600	Atorvastatin 80 mg	58	78	100	42	NR

		Usual care	59	79	100	44	NR
PROSPER (2002) ⁹	5,804	Pravastatin 40 mg	75.4	48.3	45.2	62.2	26.0
		Placebo	75.3	48.3	43.2	61.6	27.6
HPS (2003) ¹⁰	20,536	Simvastatin 40 mg	87	86	87	—	—
		Placebo	23	18	22	—	—
ASCOT-LLA (2003) ¹¹	10,342	Atorvastatin 10 mg	63.1	81.1	0.0	—	33.2
		Placebo	63.2	81.3	0.0	—	32.2
A to Z (2004) ¹²	4,497	Simvastatin 20mg	61	75	16	50	41
		Simvastatin 40/80 mg	61	76	18	50	41
PROVE IT (2004) ¹³	4,162	Pravastatin 40 mg	58.3	78.4	100	49.2	37.1
		Atorvastatin 80 mg	58.1	77.8	100	51.3	36.4
IDEAL (2005) ¹⁴	8,888	Simvastatin 20 mg	61.6	80.8	100	33.0	21.2
		Atorvastatin 80 mg	61.8	80.9	100	32.9	20.1
TNT (2005) ¹⁵	10,001	Atorvastatin 80 mg	61.2	81.2	100	53.9	13.4
		Atorvastatin 10 mg	60.9	80.8	100	54.4	13.4
MEGA (2006) ¹⁶	7,832	Pravastatin 10-20 mg	58.2	32	0.0	42	21
		Usual care	58.4	31	0.0	42	20

CORONA (2007) ¹⁷	5,011	Rosuvastatin 10 mg	73	76	100	63	9
		Placebo	73	76	100	63	8
GISSI-HF (2008) ¹⁸	4,631	Rosuvastatin 10 mg	68	76.2	31.8	55.1	14.1
		Placebo	68	78.6	33.8	53.5	14.0
JUPITER (2008) ¹⁹	17,802	Rosuvastatin 20 mg	66	5474	0.0	—	—
		Placebo	66	5527	0.0	—	—
ASTRONOMER (2010) ²⁰	269	Rosuvastatin 40 mg	58.0	60.5	0.0	—	11.2
		Placebo	57.9	63.0	0.0	—	10.4
SEARCH (2010) ²¹	12,064	Simvastatin 80 mg	64 (9)	83	100	42	30
		Simvastatin 20 mg					
ODYSSEY OPTIONS I (2015) ²²	355	Alirocumab 75/150 mg every 2 weeks	63.1	61.5	52.9	76.9	—
		Ezetimibe	62.8	66.5	57.8	78.9	—
ODYSSEY FH I (2015) ²³	486	Alirocumab 75 mg every 2 weeks	52.1	180	147	139	39
		Placebo	51.7	94	78	71	30
ODYSSEY FH II (2015) ²³	249	Alirocumab 75 mg every 2 weeks	53.2	86	58	57	36

		Placebo	53.2	45	31	24	13
ODYSSEY LONG TERM (2015) ²⁴	2,341	Alirocumab 150 mg every 2 weeks	60.4	983	1055	—	325
		Placebo	60.6	474	552	—	159
OSLER (2015) ²⁵	4,465	Evolocumab 140 mg every 2 weeks or 420 mg monthly	57.8	1490	589	1545	465
		Placebo	58.2	765	307	777	222
GLAGOV (2016) ²⁶	968	Evolocumab 420 mg monthly	59.8	349	484	398	124
		Placebo	59.8	350	484	405	113
ODYSSEY CHOICE I (2016) ²⁷	803	Alirocumab 300 mg monthly or 75 mg every 2 weeks	59.2	80	40	—	—
		Placebo	59.4	40	20	—	—
ODYSSEY JAPAN (2016) ²⁸	206	Alirocumab 150 mg every 2 weeks	60.3	84	18	—	—
		Placebo	61.8	47	8	—	—
YUKAWA-2 (2016) ²⁹	404	Evolocumab 140 mg every 2 weeks or 420 mg monthly	62.0	60	15	75	23
		Placebo	61.0	61	11	72	26

ODYSSEY OPTIONS II (2016) ³⁰	305	Alirocumab 75 mg every 2 weeks	59.9	57	53	74	—
		Usual care	61.3	63	60	72	—
FOURIER (2017) ³¹	27,564	Evolocumab 140 mg every 2 weeks or 420 mg monthly	62.5	75.4	80.9	80.1	28.0
		Placebo	62.5	75.5	81.3	80.1	28.5
ODYSSEY OUTCOMES (2018) ³²	18,924	Alirocumab 75-150 mg every 2 weeks	58.5	74.7	100	65.6	24.1
		Placebo	58.6	74.9	100	63.9	24.1

Table S4. Analyses According to Fixed Effects Model.

Analysis	Studies	Patients	RR [95% CI]	P-interaction
Risk of Incident DM in Total Population				
More intensive lipid lowering therapy	33	163,688	1.07 [1.03, 1.11]	0.02
Statins	21	124,755	1.10 [1.05, 1.15]	
PCSK9 Inhibitors	12	38,933	1.00 [0.93, 1.07]	
Subgroup Analysis According to Weighted Between-Group Difference in LDL-C Achieved				
0.51 mmol/L	5	32,752	1.11 [1.03, 1.19]	0.08
1.15 mmol/L	16	92,003	1.09 [1.03, 1.16]	
1.58 mmol/L	12	38,933	1.00 [0.93, 1.07]	
Sensitivity Analysis According to Statins Subgroups				
High intensity statin versus low intensity statin	5	32,752	1.11 [1.03, 1.19]	0.72
Statin vs no statin	16	92,003	1.09 [1.03, 1.16]	
Trials with sample size of ≥ 500 patients which reported outcome at follow-up ≥ 1 year				
More intensive lipid lowering therapy	25	161,531	1.07 [1.03, 1.11]	0.03
Statins	20	124,486	1.10 [1.05, 1.15]	
PCSK9 Inhibitors	5	37,045	1.00 [0.93, 1.08]	

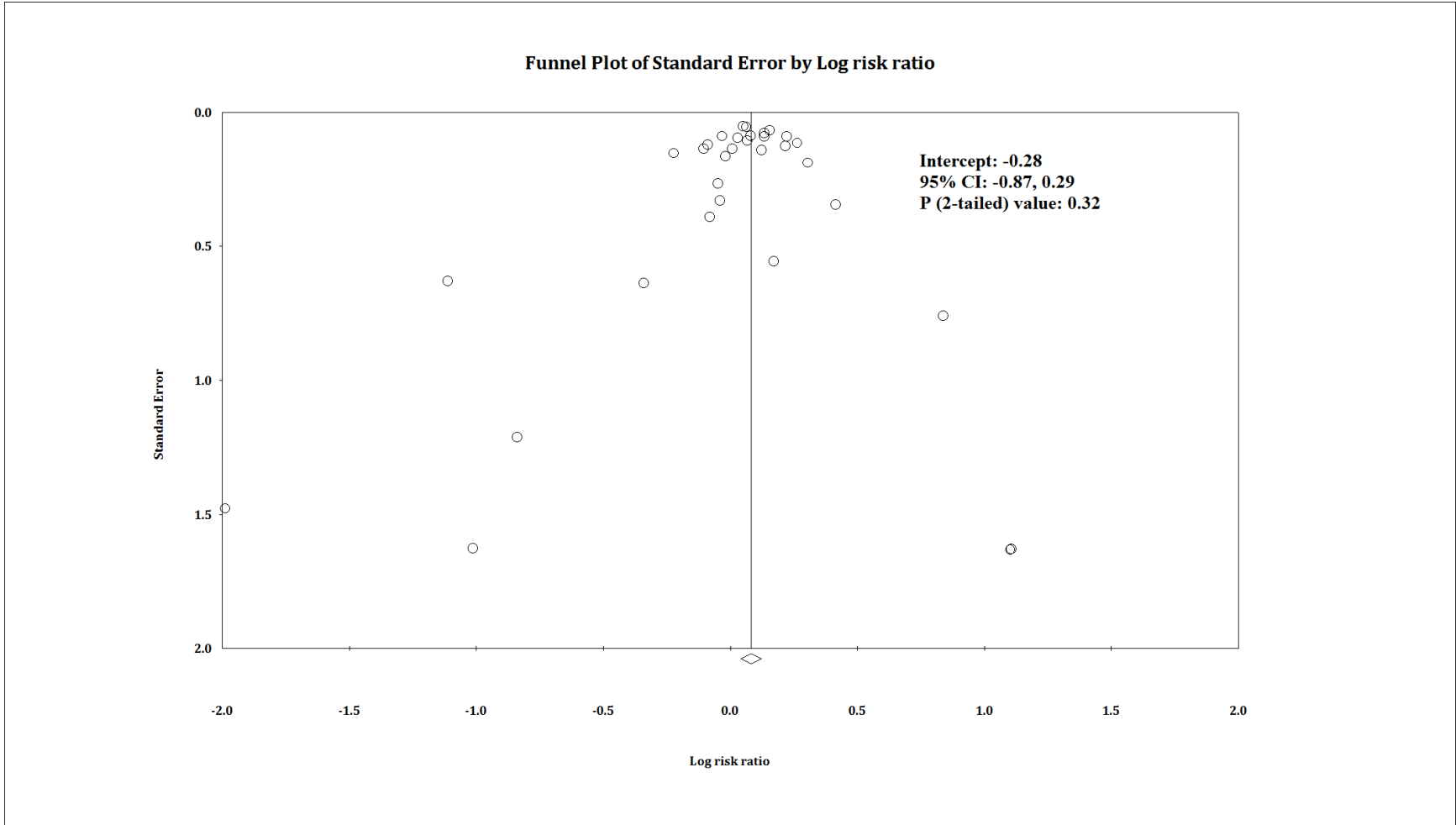
*P-interaction corresponds to statin and PCSK9 inhibitor subgroup interaction

Table S5. Sensitivity Analyses According to Year of Publication and Definition of Diabetes Mellitus.

	Studies	Patients	Risk Ratio [95% CI]			*P interaction
			More intensive lipid lowering therapy	Statin	PCSK9 Inhibitor	
Cumulative Meta-Analysis Accounting for the Year of the Trial Publication						
Original meta-analysis	33	163,688	1.07 [1.03, 1.11]	1.10 [1.05, 1.15]	1.00 [0.93, 1.07]	0.02
4S and WOSCOPS excluded	31	153,472	1.08 [1.04, 1.12]	1.11 [1.06, 1.17]	1.00 [0.93, 1.07]	0.01
Year before 2000 excluded	28	139,202	1.08 [1.04, 1.13]	1.13 [1.07, 1.18]	1.00 [0.93, 1.07]	0.006
Year before 2010 excluded	14	49,999	1.02 [0.96, 1.08]	1.07 [0.96, 1.19]	1.00 [0.93, 1.07]	0.31
Meta-Analysis Stratified According to Definition of Diabetes Mellitus						
Two FBG levels \geq 126 mg/dL	11	89,303	1.10 [1.04, 1.16]	1.11 [1.05, 1.18]	1.05 [0.95, 1.17]	0.37
Medication/Adverse events	14	45,625	1.07 [0.97, 1.18]	1.08 [0.98, 1.19]	0.96 [0.61, 1.51]	0.62
Adverse events only	8	28,760	1.00 [0.92, 1.08]	1.08 [0.95, 1.23]	0.95 [0.86, 1.05]	0.12

*P-interaction corresponds to statin and PCSK9 inhibitor subgroup interaction. FBG (Fasting Blood Glucose)

Figure S1. Funnel plot for publication bias assessment.



Supplemental References:

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