

Clinical trials of ezetimibe

TrialResults-center www.trialresultscenter.org

1 post myocardial infarction

Trial	Treatments	Patients	Trials design and methods
ezetimibe vs placebo (on top statins)			
IMPROVE-IT , 2014 [NCT00202878] n=9067/9077 follow-up: 5.68 years	10 mg/day of ezetimibe and 40 mg/day of simvastatin versus simvastatin 40 mg/day	subjects with stabilized high-risk acute coronary syndrome	Parallel groups double blind 39 countries

More details and results :

- cholesterol lowering intervention for post myocardial infarction in all type of patients at <http://www.trialresultscenter.org/go-Q45>

References

IMPROVE-IT, 2014:

Cannon CP, Blazing MA, Giugliano RP, McCagg A, White JA, Theroux P, Darius H, Lewis BS, Ophuis TO, Jukema JW, De Ferrari GM, Ruzyllo W, De Lucca P, Im K, Bohula EA, Reist C, Wiviott SD, Tershakovec AM, Musliner TA, Braunwald E, Califf RM Ezetimibe Added to Statin Therapy after Acute Coronary Syndromes. N Engl J Med 2015;372:2387-97 [26039521]

2 cardiovascular prevention

Trial	Treatments	Patients	Trials design and methods
ezetimibe+simvastatin vs placebo			
SHARP , 2010 [NCT00125593] n=4193/4191 follow-up: 4.9 years	Simvastatin 20mg/Ezetimibe 10mg versus placebo	patients with established chronic kidney disease (dialysis or pre-dialysis)	Parallel groups double-blind 20 countries
SEAS , 2008 [NCT00092677] n=944/929 follow-up: 52.2 mo	simvastatin 40mg plus ezetimibe 10 mg daily versus placebo	patients with mild-to-moderate, asymptomatic aortic stenosis	Parallel groups double blind Europe

continued...

Trial	Treatments	Patients	Trials design and methods
ezetimibe vs placebo (on top statins)			
Enhance , 2008 n=357/363 follow-up: 24 months	ezetimibe 10mg + simvastatin daily versus simvastatin 80mg daily	patients with familial hypercholesterolemia	Parallel groups double blind
IMPROVE-IT , 2014 [NCT00202878] n=9067/9077 follow-up: 5.68 years	10 mg/day of ezetimibe and 40 mg/day of simvastatin versus simvastatin 40 mg/day	subjects with stabilized high-risk acute coronary syndrome	Parallel groups double blind 39 countries
ezetimibe vs niacin			
ARBITER-HALTS 6 , 2010 n=NA follow-up: 14 months	addition of ezetimibe (10 mg/daily) to statin therapy versus extended-release niacin 2000 mg/daily	patients at high risk for vascular disease but with LDL-cholesterol levels <100 mg/dL and moderately low HDL-cholesterol levels (<50 mg/dL)	Parallel groups open
niacin+ezetimibe vs simvastatin+ezetimibe			
Guyton , 2008 n=NA follow-up: 24 weeks	Niacin 2 g ezetimibe 10 mg simvastatin 20 mg versus Ezetimibe 10 mg simvastatin 20 mg	patients with type IIa or IIb hyperlipidemia	Parallel groups double-blind

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More details and results :

- cholesterol lowering intervention for cardiovascular prevention in high risk patients with or without LDL cholesterol elevation at <http://www.trialresultscenter.org/go-Q11>
- cholesterol lowering intervention for cardiovascular prevention in patients with prior MI or with CHD at <http://www.trialresultscenter.org/go-Q12>
- cholesterol lowering intervention for cardiovascular prevention in patient with related disease at <http://www.trialresultscenter.org/go-Q137>
- cholesterol lowering intervention for cardiovascular prevention in all chronical situations at <http://www.trialresultscenter.org/go-Q154>
- cholesterol lowering intervention for cardiovascular prevention in patients with renal insufficiency (on hemodialysis or transplant) at <http://www.trialresultscenter.org/go-Q284>
- niacin for cardiovascular prevention in all type of patients at <http://www.trialresultscenter.org/go-Q326>
- on top statins for cardiovascular prevention in all type of patients at <http://www.trialresultscenter.org/go-Q722>

References

SHARP, 2010:

Sharp Collaborative Group Study of Heart and Renal Protection (SHARP): Randomized trial to assess the effects of lowering low-density lipoprotein cholesterol among 9,438 patients with chronic kidney disease. *Am Heart J* 2010 Nov;160:785-794.e10 [21095263] [10.1016/j.ahj.2010.08.012](https://doi.org/10.1016/j.ahj.2010.08.012)

Baigent C, Landray MJ, Reith C, Emberson J, Wheeler DC, Tomson C, Wanner C, Krane V, Cass A, Craig J, Neal B, Jiang L, Hooi LS, Levin A, Agodoa L, Gaziano M, Kasiske B, Walker R, Massy ZA, Feldt-Rasmussen B, Kairittichai U, Ophascharoensuk V, Fellström B The effects of lowering LDL cholesterol with simvastatin plus ezetimibe in patients with chronic kidney disease (Study of Heart and Renal Protection): a randomised placebo-controlled trial. *Lancet* 2011 Jun 25;377:2181-2192 [21663949] [10.1016/S0140-6736\(11\)60739-3](https://doi.org/10.1016/S0140-6736(11)60739-3)

SEAS, 2008:

Rosseb AB, Pedersen TR, Boman K, Brudi P, Chambers JB, Egstrup K, Gerds E, Gohlke-Brwolf C, Holme I, Kesniemi YA, Malbecq W, Nienaber CA, Ray S, Skjaerpe T, Wachtell K, Willenheimer R Intensive lipid lowering with simvastatin and ezetimibe in aortic stenosis. *N Engl J Med* 2008 Sep 25;359:1343-56 [18765433]

Enhance, 2008:

Kastelein JJ, Akdim F, Stroes ES, Zwinderman AH, Bots ML, Stalenhoef AF, Visseren FL, Sijbrands EJ, Trip MD, Stein EA, Gaudet D, Duivenvoorden R, Veltri EP, Marais AD, de Groot E Simvastatin with or without ezetimibe in familial hypercholesterolemia. *N Engl J Med* 2008 Apr 3;358:1431-43 [18376000]

IMPROVE-IT, 2014:

Cannon CP, Blazing MA, Giugliano RP, McCagg A, White JA, Theroux P, Darius H, Lewis BS, Ophuis TO, Jukema JW, De Ferrari GM, Ruzyllo W, De Lucca P, Im K, Bohula EA, Reist C, Wiviott SD, Tereshakovec AM, Musliner TA, Braunwald E, Califf RM Ezetimibe Added to Statin Therapy after Acute Coronary Syndromes. *N Engl J Med* 2015;372:2387-97 [26039521]

ARBITER-HALTS 6, 2010:

[10.1016/j.jacc.2010.03.017](https://doi.org/10.1016/j.jacc.2010.03.017)

Guyton, 2008:

Guyton JR, Brown BG, Fazio S, Polis A, Tomassini JE, Tereshakovec AM Lipid-altering efficacy and safety of ezetimibe/simvastatin coadministered with extended-release niacin in patients with type IIa or type IIb hyperlipidemia. *J Am Coll Cardiol* 2008;51:1564-72 [18420099] [10.1016/j.jacc.2008.03.003](https://doi.org/10.1016/j.jacc.2008.03.003)

3 acute coronary syndrome

Trial	Treatments	Patients	Trials design and methods
ezetimibe vs placebo (on top statins)			
IMPROVE-IT , 2014 [NCT00202878] n=9067/9077 follow-up: 5.68 years	10 mg/day of ezetimibe and 40 mg/day of simvastatin versus simvastatin 40 mg/day	subjects with stabilized high-risk acute coronary syndrome	Parallel groups double blind 39 countries

More details and results :

- cholesterol lowering intervention for acute coronary syndrome in early initiation at <http://www.trialresultscenter.org/go-Q21>

References

IMPROVE-IT, 2014:

Cannon CP, Blazing MA, Giugliano RP, McCagg A, White JA, Theroux P, Darius H, Lewis BS, Ophuis TO, Jukema JW, De Ferrari GM, Ruzyllo W, De Lucca P, Im K, Bohula EA, Reist C, Wiviott SD, Tershakovec AM, Musliner TA, Braunwald E, Califf RM Ezetimibe Added to Statin Therapy after Acute Coronary Syndromes. N Engl J Med 2015;372:2387-97 [26039521]

4 familial hypercholesterolemia

Trial	Treatments	Patients	Trials design and methods
ezetimibe vs placebo (on top statins)			
Enhance , 2008 n=357/363 follow-up: 24 months	ezetimibe 10mg + simvastatin daily versus simvastatin 80mg daily	patients with familial hypercholesterolemia	Parallel groups double blind

More details and results :

- cholesterol lowering intervention for familial hypercholesterolemia in all type of patients at <http://www.trialresultscenter.org/go-Q136>

References

Enhance, 2008:

Kastelein JJ, Akdim F, Stroes ES, Zwinderman AH, Bots ML, Stalenhoef AF, Visseren FL, Sijbrands EJ, Trip MD, Stein EA, Gaudet D, Duivenvoorden R, Veltri EP, Marais AD, de Groot E Simvastatin with or without ezetimibe in familial hypercholesterolemia. N Engl J Med 2008 Apr 3;358:1431-43 [18376000]

5 aortic stenosis

Trial	Treatments	Patients	Trials design and methods
ezetimibe+simvastatin vs placebo			
SEAS , 2008 [NCT00092677] n=944/929 follow-up: 52.2 mo	simvastatin 40mg plus ezetimibe 10 mg daily versus placebo	patients with mild-to-moderate, asymptomatic aortic stenosis	Parallel groups double blind Europe

More details and results :

- cholesterol lowering intervention for aortic stenosis in all type of patients at <http://www.trialresultscenter.org/go-Q385>

References

SEAS, 2008:

Rosseb AB, Pedersen TR, Boman K, Brudi P, Chambers JB, Egstrup K, Gerds E, Gohlke-Brwolf C, Holme I, Kesniemi YA, Malbecq W, Nienaber CA, Ray S, Skjaerpe T, Wachtell K, Willenheimer R Intensive lipid lowering with simvastatin and ezetimibe in aortic stenosis. N Engl J Med 2008 Sep 25;359:1343-56 [18765433]

Entry terms: niacin, Niacin, Nicotinic Acid, 3-Pyridinecarboxylic Acid, 3 Pyridinecarboxylic Acid, Induracin, Nicamin, Nico-400, Nico 400, Nico400, Nicobid, Nicocap, Nicolac, Nicotinate, Wampocap, Enduracin, Lithium Nicotinate, Zetia, Ezetrol, simvastatin, Zocor, atorvastatin, Lipitor