

Clinical trials of insulin sensitizers - glitazones for diabetes type 2 in patients with cardiovascular disease

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1 thiazolidinediones

Trial	Treatments	Patients	Trials design and methods
rosiglitazone vs control			
Wang , 2005 n=NA follow-up: 6 months	rosiglitazone 4 mg/d versus control	patients with diabetes and CAD who had undergone percutaneous coronary intervention	Parallel groups open
pioglitazone vs placebo			
PROactive , 2005 [NCT00174993] n=2605/2633 follow-up: 34.5 mo	pioglitazone titrated from 15 mg to 45 mg versus placebo	Inadequately controlled patients with type 2 diabetes who had evidence of macrovascular disease	Parallel groups double blind 19 European countries
rosiglitazone pioglitazone vs placebo			
TIDE <i>ongoing</i> [NCT00879970] n=16000 follow-up:	pioglitazone or rosiglitazone versus placebo	patients with type 2 diabetes who have a history of or are at risk for cardiovascular disease	Factorial plan double-blind USA
pioglitazone vs standard glucose-lowering drugs			
PPAR <i>ongoing</i> [NCT00212004] n=NA follow-up:	pioglitazone versus sulfonylurea agents	diabetes patients with a history of prior myocardial infarction	Parallel groups Japan
pioglitazone vs sulfonylurea			
OPI-504 [NCT00521820] n=262/256 follow-up: 24 wk	Pioglitazone versus Sulfonylurea	patients with type 2 diabetes and mild to moderate congestive heart failure	Parallel groups
OPI-520 [NCT00521742] n=151/149 follow-up: 52 wk	Pioglitazone versus Sulfonylurea	Inadequately controlled DM-2 with mild cardiac disease(New York Heart Association Class I)	Parallel groups
pioglitazone vs glimepiride			
PERISCOPE , 2008 [NCT00225277] n=274/273 follow-up: 18 months	pioglitazone 15 to 45 mg versus glimepiride, 1 to 4 mg	patients with coronary disease and type 2 diabetes	Parallel groups double blind North and South America
rosiglitazone vs glipizide			

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Trial	Treatments	Patients	Trials design and methods
APPROACH , 2008 [NCT00116831] n=333/339 follow-up: 18 months	rosiglitazone at up to 8 mg/day versus glipizide at 15 mg/day	patients with type 2 diabetes and coronary artery disease	Parallel groups double blind

References

Wang, 2005:

Wang G, Wei J, Guan Y, Jin N, Mao J, Wang X, Peroxisome proliferator-activated receptor-gamma agonist rosiglitazone reduces clinical inflammatory responses in type 2 diabetes with coronary artery disease after coronary angioplasty. *Metabolism* 2005;54:590-7. [[15877288](#)] [10.1016/j.metabol.2004.11.017](https://doi.org/10.1016/j.metabol.2004.11.017)

PROactive, 2005:

Dormandy JA, Charbonnel B, Eckland DJ, Erdmann E, Massi-Benedetti M, Moules IK, Skene AM, Tan MH, Lefebvre PJ, Murray GD, Standl E, Wilcox RG, Wilhelmsen L, Betteridge J, Birkeland K, Golay A, Heine RJ, Koranyi L, Laakso M, Morkan M, Norkus A, Pirags V, Po Secondary prevention of macrovascular events in patients with type 2 diabetes in the PROactive Study (PROspective pioglitAzone Clinical Trial In macroVascular Events): a randomised controlled trial. *Lancet* 2005 Oct 8;366:1279-89 [[16214598](#)]

TIDE, :

PPAR, :

OPI-504, :

OPI-520, :

PERISCOPE, 2008:

Nissen SE, Nicholls SJ, Wolski K, Nesto R, Kupfer S, Perez A, Jure H, De Laroche R, Staniloae CS, Mavromatis K, Saw J, Hu B, Lincoff AM, Tuzcu EM Comparison of pioglitazone vs glimepiride on progression of coronary atherosclerosis in patients with type 2 diabetes: the PERISCOPE randomized controlled trial. *JAMA* 2008 Apr 2;299:1561-73 [[18378631](#)]

Nicholls SJ, Tuzcu EM, Wolski K, Bayturan O, Lavoie A, Uno K, Kupfer S, Perez A, Nesto R, Nissen SE Lowering the triglyceride/high-density lipoprotein cholesterol ratio is associated with the beneficial impact of pioglitazone on progression of coronary atherosclerosis in diabetic patients: insights from the PERISCOPE (Pioglitazone Effect on Regression of Intravascular Sonographic Coronary Obstruction Prospective Evaluation) study. *J Am Coll Cardiol* 2011;57:153-9 [[21211686](#)] [10.1016/j.jacc.2010.06.055](https://doi.org/10.1016/j.jacc.2010.06.055)

APPROACH, 2008:

Ratner RE, Cannon CP, Gerstein HC, Nesto RW, Serruys PW, Van Es GA, Kolatkar NS, Kravitz BG, Zalewski A, Fitzgerald PJ Assessment on the Prevention of Progression by Rosiglitazone on Atherosclerosis in diabetes patients with Cardiovascular History (APPROACH): study design and baseline characteristics. *Am Heart J* 2008;156:1074-9 [[19033001](#)]

Gerstein HC, Ratner RE, Cannon CP, Serruys PW, Garca-Garca HM, van Es GA, Kolatkar NS, Kravitz BG, Miller DM, Huang C, Fitzgerald PJ, Nesto RW Effect of rosiglitazone on progression of coronary atherosclerosis in patients with type 2 diabetes mellitus and coronary artery disease: the assessment on the prevention of progression by rosiglitazone on atherosclerosis in diabetes patients with cardiovascular history trial. *Circulation* 2010;121:1176-87 [[20194881](#)] [10.1161/CIRCULATIONAHA.109.881003](https://doi.org/10.1161/CIRCULATIONAHA.109.881003)

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.

Rigorous meta-analysis method is used to populate TrialResults-center: widespread search of published and non published trials, study selection using pre-specified criteria, data extraction using standard form.

TrialResults-center is continually updated on a weekly basis. We continually search all new results (whatever their publication channel) and these news results are immediately added to the database with a maximum of 1 week.

TrialResults-center is non-profit and self-funded.