

Clinical trials of pioglitazone

TrialResults-center www.trialresultscenter.org

1 diabetes type 2

Trial	Treatments	Patients	Trials design and methods
pioglitazone vs metformin			
EC404 n=597/597 follow-up: 52 wk	Pioglitazone versus Metformin	patients with type 2 diabetes	Parallel groups
pioglitazone + sulfonyleurea vs metformin + sulfonyleurea			
EC409 n=319/320 follow-up: 104 wk	Pioglitazone + sulfonyleurea versus Metformin + sulfonyleurea	patients with type 2 diabetes	Parallel groups
pioglitazone vs placebo			
PROACTIVE [NCT00174993] n=2605/2633 follow-up: 34.5 months	oral pioglitazone titrated from 15 mg to 45 mg versus placebo	patients with type 2 diabetes who had evidence of macrovascular disease.	
IRIS , 2016 [NCT00091949] n=NA	-	-	
PNFP-001 n=329/79 follow-up: 26 wk	Pioglitazone versus Placebo	patients with type 2 diabetes	Parallel groups
PNFP-012 n=176/84 follow-up: 24 wk	Pioglitazone versus Placebo	patients with type 2 diabetes	Parallel groups
PNFP-026 n=101/96 follow-up: 16 wk	Pioglitazone versus Placebo	patients with type 2 diabetes	Parallel groups
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
pioglitazone + insulin vs placebo (add on insulin)			

continued...

Trial	Treatments	Patients	Trials design and methods
OPI-502 n=110/112 follow-up: 20 wk	Pioglitazone + insulin versus Placebo + insulin	Insulin-dependent DM-2	Parallel groups
PNFP-014 n=379/187 follow-up: 16 wk	Pioglitazone insulin versus Placebo + insulin	patients with type 2 diabetes	Parallel groups
pioglitazone + metformin vs placebo (add on MET)			
PNFP-027 n=168/160 follow-up: 16 wk	Pioglitazone + metformin versus Placebo + metformin	patients with type 2 diabetes	Parallel groups
pioglitazone vs rosiglitazone			
GLAI [NCT00331487] n=369/366 follow-up: 24 wk	Pioglitazone versus Rosiglitazone	patients with type 2 diabetes and dyslipidemia	Parallel groups
pioglitazone vs sulfonylurea			
EC405 n=624/626 follow-up: 52 wk	Pioglitazone versus Sulfonylurea	patients with type 2 diabetes	Parallel groups
OPI-501 n=251/251 follow-up: 56 wk	Pioglitazone versus Sulfonylurea	Recently diagnosed DM-2	Parallel groups
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-506 [NCT00494312] n=1051/1046 follow-up: 156 wk	Pioglitazone versus Sulfonylurea	Inadequately controlled DM-2	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 + sulfonylurea vs sulfonylurea			
PNFP-010 n=373/187 follow-up: 16 wk	Pioglitazone + sulfonylurea versus Sulfonylurea	patients with type 2 diabetes	Parallel groups
pioglitazone + metformin vs sulfonylurea + metformin			

continued...

Trial	Treatments	Patients	Trials design and methods
EC410 n=317/313 follow-up: 104 wk	Pioglitazone + metformin versus Sulfonylurea + metformin	patients with type 2 diabetes	Parallel groups
pioglitazone vs vildagliptin			
Bolli , 2008 n=295/295 follow-up: 52 weeks	vildagliptin (50 mg b.i.d.) versus pioglitazone (30 mg daily)	-	
rosiglitazone pioglitazone vs placebo			
TIDE ongoing [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 ongoing [NCT00212004] n=NA follow-up:	pioglitazone versus sulfonylurea agents	diabetes patients with a history of prior myocardial infarction	Parallel groups Japan
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
linagliptin + pioglitazone vs pioglitazone			
linagliptin 1264.3 ongoing [NCT01183013] n=NA follow-up: 30 weeks	linagliptin/pioglitazone (5/15, 5/30 and 5/45 mg) linagliptine versus pioglitazone	-	

More details and results :

- insulin sensitizers - glitazones for diabetes type 2 in all type of patients at <http://www.trialresultscenter.org/go-Q321>
- insulin sensitizers - glitazones for diabetes type 2 in patients with cardiovascular disease at <http://www.trialresultscenter.org/go-Q376>
- insulin sensitizer for diabetes type 2 in all type of patients at <http://www.trialresultscenter.org/go-Q377>
- insulin sensitizer for diabetes type 2 in patients with cardiovascular disease at <http://www.trialresultscenter.org/go-Q378>
- insulin secretagogues for diabetes type 2 in all type of patients at <http://www.trialresultscenter.org/go-Q409>

- antidiabetic drugs for diabetes type 2 in patients inadequately controlled on monotherapy at <http://www.trialresultscenter.org/go-Q512>
- antidiabetic drugs for diabetes type 2 in patients inadequately controlled with insulin at <http://www.trialresultscenter.org/go-Q513>
- insulin secretagogues - DPP-4 inhibitors for diabetes type 2 in all types of patients at <http://www.trialresultscenter.org/go-Q550>
- glucose lowering for cardiovascular prevention for diabetes type 2 in all type of patients at <http://www.trialresultscenter.org/go-Q576>
- glucose lowering for cardiovascular prevention for diabetes type 2 in meta-regression at <http://www.trialresultscenter.org/go-Q692>

References

EC404, :

EC409, :

PROACTIVE, :

Dormandy JA, Charbonnel B, Eckland DJ, Erdmann E, Massi-Benedetti M, Moules IK, Skene AM, Tan MH, Lefbvre PJ, Murray GD, Standl E, Wilcox RG, Wilhelmsen L, Betteridge J, Birkeland K, Golay A, Heine RJ, Kornyi L, Laakso M, Mokn 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;366:1279-89 [16214598]

IRIS, 2016:

Kernan WN, Viscoli CM, Furie KL, Young LH, Inzucchi SE, Gorman M, Guarino PD, Lovejoy AM, Peduzzi PN, Conwit R, Brass LM, Schwartz GG, Adams HP Jr, Berger L, Carolei A, Clark W, Coull B, Ford GA, Kleindorfer D, O'Leary JR, Parsons MW, Ringleb P, Sen S, Sp Pioglitazone after Ischemic Stroke or Transient Ischemic Attack. N Engl J Med 2016 Apr 7;374:1321-31 [26886418] 10.1056/NEJMoa1506930

PNFP-001, :

PNFP-012, :

PNFP-026, :

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, Mogan 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]

OPI-502, :

PNFP-014, :

PNFP-027, :

GLAI, :

EC405, :

OPI-501, :

OPI-504, :

OPI-506, 0:

OPI-520, :

PNFP-010, :

EC410, :

Bolli, 2008:

Bolli G, Dotta F, Rochotte E, Cohen SE Efficacy and tolerability of vildagliptin vs. pioglitazone when added to metformin: a 24-week, randomized, double-blind study. *Diabetes Obes Metab* 2008;10:82-90 [[18034842](#)] [10.1111/j.1463-1326.2007.00820.x](#)

Bolli G, Dotta F, Colin L, Minic B, Goodman M Comparison of vildagliptin and pioglitazone in patients with type 2 diabetes inadequately controlled with metformin. *Diabetes Obes Metab* 2009;11:589-95 [[19515179](#)] [10.1111/j.1463-1326.2008.01023.x](#)

TIDE, :

ongoing trial NCT00879970

PPAR, :

ongoing trial NCT00212004

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](#)

linagliptin 1264.3, 0:

ongoing trial NCT01183013

Entry terms: Actos, linagliptin, Linagliptin, Tradjenta, BI 1356, BI1356, BI-1356,