

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>

References

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EC409, :

PROACTIVE, :

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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, Moka 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](#)

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linagliptin 1264.3, 0:

ongoing trial NCT01183013

Entry terms: Actos