

Clinical trials of rosiglitazone

TrialResults-center www.trialresultscenter.org

1 diabetes type 2

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---------------------------|
| rosiglitazone vs | | | |
| AVM100264 [NCT00359112] n=294/302 follow-up: 52 wk | Rosiglitazone and metformin versus Metformin and sulfonylurea | Overweight patients with type 2 DM poorly controlled on Met | Parallel groups |
| BRL 49653C/185 n=563/142 follow-up: 32 wk | Rosiglitazone with or without metformin versus Usual care with or without metformin | patients with type 2 diabetes | Parallel groups |
| SB-712753/007 n=314/154 follow-up: 32 wk | Rosiglitazone with or without metformin versus Metformin | patients with type 2 diabetes without previous drug therapy | Parallel groups |
| SB-712753/009 n=162/160 follow-up: 24 wk | Rosiglitazone, metformin, and insulin versus Insulin | patients with type 2 diabetes with insulin | Parallel groups |
| 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 |
| rosiglitazone vs glyburide | | | |
| 49653/020 n=391/207 follow-up: 52 wk | Rosiglitazone versus Glyburide | patients with type 2 diabetes | Parallel groups |
| 49653/079 n=203/106 follow-up: 26 wk | Rosiglitazone with or without glyburide versus Glyburide | patients with type 2 diabetes poorly controlled on maximum dose of Gly | Parallel groups |
| 49653/080 n=104/99 follow-up: 156 wk | Rosiglitazone versus Glyburide | patients with type 2 diabetes | Parallel groups |
| 49653/097 n=122/120 follow-up: 156 wk | Rosiglitazone versus Glyburide | patients with type 2 diabetesDM | Parallel groups |

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| Trial | Treatments | Patients | Trials design and methods |
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| 49653/143 [NCT00333723] n=121/124 follow-up: 24 wk | Rosiglitazone and glyburide versus Glyburide | Type 2 DM poorly controlled on glyburide | Parallel groups |
| rosiglitazone vs glyburide (add on MET) | | | |
| 49653/137 [NCT00500955] n=204/185 follow-up: 32 wk | Rosiglitazone and metformin versus Glyburide and metformin | patients with type 2 diabetes | Parallel groups |
| rosiglitazone vs metformin | | | |
| 49653/093 n=213/109 follow-up: 26 wk | Rosiglitazone with or without metformin versus Metformin | patients with type 2 diabetes poorly controlled on Met | Parallel groups |
| 49653/094 n=232/116 follow-up: 26 wk | Rosiglitazone and metformin versus Metformin | Type 2 DM poorly controlled on Met | Parallel groups |
| rosiglitazone vs metformin/sulfonylurea | | | |
| RECORD , 2013 [NCT00379769] n=NA follow-up: | - | - | |
| rosiglitazone vs placebo | | | |
| 49653/011 n=357/176 follow-up: 24 wk | Rosiglitazone versus Placebo | patients with type 2 diabetes | Parallel groups |
| DREAM rosiglitazone , 2006 [NCT00095654] n=2365/2634 follow-up: 3 years (median) | rosiglitazone 8 mg daily versus placebo | patients with impaired fasting glucose or impaired glucose tolerance, or both | Parallel groups double blind 21 countries |
| 49653/128 n=39/38 follow-up: 28 wk | Rosiglitazone versus Placebo | patients with type 2 diabetes on concurrent Su | Parallel groups |
| 49653/134 n=561/276 follow-up: 28 wk | Rosiglitazone versus Placebo | patients with type 2 diabetes on Gly and Met | Parallel groups |
| 49653/136 n=148/143 follow-up: 26 wk | Rosiglitazone versus Placebo | patients with type 2 diabetes and chronic renal failure on Su, insulin, or both | Parallel groups |

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| Trial | Treatments | Patients | Trials design and methods |
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| 49653/330 n=1/382 follow-up: 52 wk | Rosiglitazone versus Placebo | Chronic psoriasis | Parallel groups |
| 49653/331 n=706/325 follow-up: 52 wk | Rosiglitazone versus Placebo | Chronic psoriasis | Parallel groups |
| AVA100193 n=394/124 follow-up: 24 wk | Rosiglitazone versus Placebo | Mild-to-moderate Alzheimers disease | Parallel groups |
| BRL 49653/334 [NCT00306644] n=278/279 follow-up: 52 wk | Rosiglitazone versus Placebo | patients with type 2 diabetes or insulin resistance syndrome | Parallel groups |
| rosiglitazone and metformin vs placebo | | | |
| CANOE , 2010 [NCT00116932] n=103/104 follow-up: 3.9y (median) | rosiglitazone (2 mg) and metformin (500 mg) twice-daily versus placebo | patients with impaired glucose tolerance | Parallel groups double-blind |
| rosiglitazone vs placebo (add on glicazide) | | | |
| 49653/145 n=231/242 follow-up: 26 wk | Rosiglitazone and gliclazide versus Gliclazide | patients with type 2 diabetes | Parallel groups |
| rosiglitazone vs placebo (add on glimepiride) | | | |
| 49653/234 n=116/61 follow-up: 26 wk | Rosiglitazone and glimepiride versus Glimepiride | patients with type 2 diabetes | Parallel groups |
| rosiglitazone vs placebo (add on glipizide) | | | |
| 49653/135 n=116/111 follow-up: 104 wk | Rosiglitazone and glipizide versus Glipizide | Elderly patients with type 2 DM | Parallel groups |
| rosiglitazone vs placebo (add on glyburide) | | | |
| 100684 [NCT01045590] n=43/47 follow-up: 52 wk | Rosiglitazone and glyburide versus Glyburide | Korean patients with type 2 DM | Parallel groups |
| 49653/127 n=56/58 follow-up: 26 wk | Rosiglitazone and glyburide versus Glyburide | patients with type 2 diabetespoorly controlled on Gly | Parallel groups |

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| Trial | Treatments | Patients | Trials design and methods |
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| 49653/162 n=168/172 follow-up: 26 wk | Rosiglitazone and glyburide versus Glyburide | patients with type 2 diabetes | Parallel groups |
| rosiglitazone vs placebo (add on insulin) | | | |
| 49653/085 n=138/139 follow-up: 26 wk | Rosiglitazone and insulin versus Insulin | patients with type 2 diabetes | Parallel groups |
| 49653/095 n=196/96 follow-up: 26 wk | Rosiglitazone and insulin versus Insulin | patients with type 2 diabetes poorly controlled on insulin | Parallel groups |
| BRL 49653/347 [NCT00054782] n=418/212 follow-up: 24 wk | Rosiglitazone and insulin versus Insulin | patients with type 2 diabetes poorly controlled on insulin | Parallel groups |
| rosiglitazone vs placebo (add on MET) | | | |
| 49653/284 [NCT00501020] n=382/384 follow-up: 24 wk | Rosiglitazone and metformin versus Metformin | patients with type 2 diabetes | Parallel groups |
| 712753/008 [NCT00241605] n=284/135 follow-up: 48 wk | Rosiglitazone and metformin versus Metformin | Type 2 DM poorly controlled on Met | Parallel groups |
| SB-712753/002 n=288/280 follow-up: 24 wk | Rosiglitazone and metformin versus Metformin | patients with type 2 diabetes poorly controlled | Parallel groups |
| SB-712753/003 n=254/272 follow-up: 32 wk | Rosiglitazone and metformin versus Metformin | Mild type 2 DM | Parallel groups |
| rosiglitazone vs placebo (add on SU) | | | |
| 49653/015 n=395/198 follow-up: 24 wk | Rosiglitazone and sulfonylurea versus Sulfonylurea | patients with type 2 diabetes | Parallel groups |
| 49653/125 [NCT00422955] n=175/173 follow-up: 26 wk | Rosiglitazone and sulfonylurea versus Sulfonylurea | patients with type 2 diabetes | Parallel groups |

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| Trial | Treatments | Patients | Trials design and methods |
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| 49653/132 n=442/112 follow-up: 24 wk | Rosiglitazone and sulfonylurea versus Sulfonylurea | Patients in China with type 2 DM | Parallel groups |
| 49653/147 n=89/88 follow-up: 26 wk | Rosiglitazone and sulfonylurea versus Sulfonylurea | Indo-Asian patients with type 2 diabetes | Parallel groups |
| rosiglitazone vs usual care | | | |
| 49653/211 n=110/114 follow-up: 52 wk | Rosiglitazone and usual care versus Usual care | Type 2 DM with CHF | Parallel groups |
| 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 |
| rosiglitazone vs glipizide | | | |
| 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 |
| rosiglitazone vs standard glucose-lowering drugs | | | |
| ADOPT , 2006 [NCT00279045] n=1456/2895 follow-up: 4y (median) | Rosiglitazone 4mg twice daily versus Metformin 1000mg twice daily or glyburide 7.5mg twice daily | Recently diagnosed type type 2 diabetes | Parallel groups double blind United States, Canada, Europe |
| RECORD , 2009 [NCT00379769] n=2220/2227 follow-up: 5.5 y | addition of rosiglitazone (4-8 mg daily titrated) to metformin or sulfonylurea, target HbA1c<=70% versus combination of metformin and sulfonylurea, target HbA1c<=70% | patients with type 2 diabetes on monotherapy with either metformin or sulfonylurea and in less than optimal blood glucose control (HbA1c >70%) | Parallel groups open Europe, Australia |

More details and results :

- insulin sensitizers - glitazones for diabetes type 2 in all type of patients at <http://www.trialresultscenter.org/go-Q321>
- prevention for diabetes type 2 in all type of patients at <http://www.trialresultscenter.org/go-Q341>
- 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>
- prevention for diabetes type 2 in people with impaired glucose tolerance at <http://www.trialresultscenter.org/go-Q416>
- antidiabetic drugs for diabetes type 2 in patients inadequately controlled with insulin at <http://www.trialresultscenter.org/go-Q513>
- glucose lowering for cardiovascular prevention for diabetes type 2 in all type of patients at <http://www.trialresultscenter.org/go-Q576>

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49653/162 , :

49653/085 , :

49653/095 , :

BRL 49653/347 , :

49653/284 , :

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2 percutaneous coronary intervention

| Trial | Treatments | Patients | Trials design and methods |
|---|------------------------------------|---|---------------------------------|
| rosiglitazone vs placebo | | | |
| PROVIDENCE <i>ongoing</i> [NCT00116792] n=NA follow-up: | Rosiglitazone versus placebo | type 2 diabetic patients with de Novo Coronary Lesions | Parallel groups double blind |

More details and results :

- restenosis prevention for percutaneous coronary intervention in all type of patients at <http://www.trialresultscenter.org/go-Q318>

References

PROVIDENCE, :

ongoing trial NCT00116792

3 impaired fasting glucose

| Trial | Treatments | Patients | Trials design and methods |
|--|---|--|---|
| rosiglitazone vs placebo | | | |
| DREAM rosiglitazone , 2006 [NCT00095654] n=2365/2634 follow-up: 3 years (median) | rosiglitazone 8 mg daily versus placebo | patients with impaired fasting glucose or impaired glucose tolerance, or both | Parallel groups double blind 21 countries |
| rosiglitazone and metformin vs placebo | | | |
| CANOE , 2010 [NCT00116932] n=103/104 follow-up: 3.9y (median) | rosiglitazone (2 mg) and metformin (500 mg) twice-daily versus placebo | patients with impaired glucose tolerance | Parallel groups double-blind |

More details and results :

- prevention for impaired fasting glucose in all type of patients at <http://www.trialresultscenter.org/go-Q342>

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Zinman B, Harris SB, Neuman J, Gerstein HC, Retnakaran RR, Raboud J, Qi Y, Hanley AJ Low-dose combination therapy with rosiglitazone and metformin to prevent type 2 diabetes mellitus (CANOE trial): a double-blind randomised controlled study. *Lancet* 2010 Jul 10;376:103-11 [20605202] 10.1016/S0140-6736(10)60746-5

Entry terms: pioglitazone, Actos, Avandia, metformin, Metformin, Dimethylguanylguanidine, Dimethylbiguanidine, Glucophage,