

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

continued...

Trial	Treatments	Patients	Trials design and methods
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
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
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
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>

References

AVM100264 , :

BRL 49653C/185 , :

SB-712753/007 , :

SB-712753/009 , :

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)

49653/020 , :

49653/079 , :

49653/080 , :

49653/097 , :

49653/143 , :

49653/137 , :

49653/093 , :

49653/094 , :

RECORD, 2013:

Home PD, Pocock SJ, Beck-Nielsen H, Curtis PS, Gomis R, Hanefeld M, Jones NP, Komajda M, McMurray JJ Rosiglitazone evaluated for cardiovascular outcomes in oral agent combination therapy for type 2 diabetes (RECORD): a multicentre, randomised, open-label trial. *Lancet* 2009 Jun 20;373:2125-35 [19501900]

Home PD, Pocock SJ, Beck-Nielsen H, Gomis R, Hanefeld M, Jones NP, Komajda M, McMurray JJ Rosiglitazone evaluated for cardiovascular outcomes—an interim analysis. *N Engl J Med* 2007 Jul 5;357:28-38 [17551159]

Mahaffey KW, Hafley G, Dickerson S, Burns S, Tourt-Uhlig S, White J, Newby LK, Komajda M, McMurray J, Bigelow R, Home PD, Lopes RD Results of a reevaluation of cardiovascular outcomes in the RECORD trial. *Am Heart J* 2013 Aug;166:240-249.e1 [23895806]

49653/011 , :

DREAM rosiglitazone, 2006:

Gerstein HC, Yusuf S, Bosch J, Pogue J, Sheridan P, Dinccag N, Hanefeld M, Hoogwerf B, Laakso M, Mohan V, Shaw J, Zinman B, Holman RR Effect of rosiglitazone on the frequency of diabetes in patients with impaired glucose tolerance or impaired fasting glucose: a randomised controlled trial. Lancet 2006 Sep 23;368:1096-105 [16997664]

49653/128 , :

49653/134 , :

49653/136 , :

49653/330 , :

49653/331 , :

AVA100193 , :

BRL 49653/334 , :

CANOE, 2010:

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

49653/145 , :

49653/234 , :

49653/135 , :

100684 , :

49653/127 , :

49653/162 , :

49653/085 , :

49653/095 , :

BRL 49653/347 , :

49653/284 , :

712753/008 , :

SB-712753/002 , :

SB-712753/003 , :

49653/015 , :

49653/125 , :

49653/132 , :

49653/147 , :

49653/211 , :

TIDE, :

ongoing trial NCT00879970

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

ADOPT, 2006:

Kahn SE, Haffner SM, Heise MA, Herman WH, Holman RR, Jones NP, Kravitz BG, Lachin JM, O'Neill MC, Zinman B, Viberti G Glycemic durability of rosiglitazone, metformin, or glyburide monotherapy. *N Engl J Med* 2006;355:2427-43 [17145742]

Kahn SE, Zinman B, Lachin JM, Haffner SM, Herman WH, Holman RR, Kravitz BG, Yu D, Heise MA, Aftring RP, Viberti G Rosiglitazone-associated fractures in type 2 diabetes: an Analysis from A Diabetes Outcome Progression Trial (ADOPT). *Diabetes Care* 2008;31:845-51 [18223031]

RECORD, 2009:

Komajda M, Curtis P, Hanefeld M, Beck-Nielsen H, Pocock SJ, Zambanini A, Jones NP, Gomis R, Home PD Effect of the addition of rosiglitazone to metformin or sulfonylureas versus metformin/sulfonylurea combination therapy on ambulatory blood pressure in people with type 2 diabetes: a randomized controlled trial (the RECORD study). *Cardiovasc Diabetol* 2008 Apr 24;7:10 [18435852]

Home PD, Pocock SJ, Beck-Nielsen H, Curtis PS, Gomis R, Hanefeld M, Jones NP, Komajda M, McMurray JJ Rosiglitazone evaluated for cardiovascular outcomes in oral agent combination therapy for type 2 diabetes (RECORD): a multicentre, randomised, open-label trial. *Lancet* 2009 Jun 5;: [19501900] 10.1016/S0140-6736(09)60953-3

Komajda M, McMurray JJ, Beck-Nielsen H, Gomis R, Hanefeld M, Pocock SJ, Curtis PS, Jones NP, Home PD Heart failure events with rosiglitazone in type 2 diabetes: data from the RECORD clinical trial. *Eur Heart J* 2010;: [20118174] 10.1093/eurheartj/ehp604

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2 percutaneous coronary intervention

Trial	Treatments	Patients	Trials design and methods
rosiglitazone vs placebo			
PROVIDENCE ongoing [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>

References

DREAM rosiglitazone, 2006:

Gerstein HC, Yusuf S, Bosch J, Pogue J, Sheridan P, Dinccag N, Hanefeld M, Hoogwerf B, Laakso M, Mohan V, Shaw J, Zinman B, Holman RR Effect of rosiglitazone on the frequency of diabetes in patients with impaired glucose tolerance or impaired fasting glucose: a randomised controlled trial. Lancet 2006 Sep 23;368:1096-105 [16997664]

CANOE, 2010:

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,