

Clinical trials of insulin sensitizer for diabetes type 2 in all type of patients

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1 biguanide

Trial	Treatments	Patients	Trials design and methods
metformin vs Acarbose			
Maji vs acarbose n=48/48 follow-up: 156	500 versus Acarbose	-	
metformin vs Glibenclamide			
Yki-Yarvinen vs glibenclamide , 1999 n=19/22 follow-up: 52	2.000 versus Glibenclamide	-	
Kahn (ADOPT) vs glibenclamide n=1454/1441 follow-up: 208	2.000 versus Glibenclamide	-	
metformin vs Glimepiride			
Yamanouchi vs glimepiride , 2005 n=39/37 follow-up: 52	750 versus Glimepiride	-	
metformin vs Glipizide/			
Vahatalo vs glipizide/glimepiride n=26/15 follow-up: 52	2.500- versus Glipizide/	-	
metformin vs Insulin			
Yki-Yarvinen vsinsulin n=19/24 follow-up: 52	2.000 versus Insulin	-	
Klein , 1991 n=25/25 follow-up: 52	2.550 versus Insulin	-	
Barnett , 2008 n=211/235 follow-up: 128	NR versus Insulin	-	
metformin vs None			
Vahatalo vs control , 2007 n=26/11 follow-up: 52	2.500 versus None	-	

continued...

Trial	Treatments	Patients	Trials design and methods
Maji vs control , 2005 n=48/90 follow-up: 156	500 versus None	-	
UKPDS 34 vs control n=342/411 follow-up: 556	2.550 versus None	-	
UKPDS 34 bis n=268/269 follow-up: 343	2.550 versus None	-	
Zhang n=49/45 follow-up: 76	750 versus None	-	
Ramachandran n=262/269 follow-up: 156	500 versus None	-	
metformin vs Pioglitazone			
Yamanouchi vs pioglitazone n=39/38 follow-up: 52	750 versus Pioglitazone	-	
Shernthaner , 2004 n=597/597 follow-up: 52	2.000 versus Pioglitazone	-	
Derosa , 2009 n=67/69 follow-up: 64	3.000 versus Pioglitazone	-	
Charbonnel , 2005 n=320/319 follow-up: 104	2.550 versus Pioglitazone	-	
metformin vs placebo			
Hermann , 2001 n=16/19 follow-up: 52 weeks	metformin 65279;1.700 versus Placebo	obese and overweight type 2 diabetes patients treated with insulin for at least 1 year, and with poor glycaemic control (HbA1c >upper reference level + 2%)	Parallel groups double-blind
Douek , 2005 n=92/91 follow-up: 52	2.000 versus Placebo	-	
Gregorio , 1999 n=89/85 follow-up: 76	1.700 versus Placebo	-	
Teupe , 1991 n=50/50 follow-up: 104	1.700 versus Placebo	Type 2 diabetic patients	Parallel groups open Canada

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Trial	Treatments	Patients	Trials design and methods
Kooy (HOME) , 2009 n=196/194 follow-up: 220	2.000 versus Placebo	Patients with type 2 diabetes	Parallel groups double blind
palomba n=15/15 follow-up: 52	1.700 versus Placebo	-	
Ibanez n=12/12 follow-up: 52	850 versus Placebo	-	
Harborne n=26/26 follow-up: 52	1.500 versus Placebo	-	
Li n=33/37 follow-up: 52	2.000 versus Placebo	-	
Martinez n=35/73 follow-up: 52	1.700 versus Placebo	-	
Gambineri n=40/40 follow-up: 52	1.700 versus Placebo	-	
Lund n=49/51 follow-up: 52	2.000 versus Placebo	-	
BIGPRO (Charles) n=164/160 follow-up: 52	1.700 versus Placebo	-	
Stakos vs placebo n=59/97 follow-up: 104	500 versus Placebo	-	
Shuster n=45/81 follow-up: 104	500 versus Placebo	-	
DPP (Knowler) n=1073/1082 follow-up: 156	1.700 versus Placebo	-	
Ibanez 62 n=19/19 follow-up: 208	425 versus Placebo	-	
metformin vs Rosiglitazone			
maji vs rosiglitazone n=48/48 follow-up: 156	500 versus Rosiglitazone	-	

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Trial	Treatments	Patients	Trials design and methods
ADOPT vs rosiglitazone n=1454/1456 follow-up: 208	2.000 versus Rosiglitazone	-	
RECORD n=1122/1103 follow-up: 260	2.550 versus Rosiglitazone	-	
Tomazic n=30/30 follow-up: 52	1.000 versus Rosiglitazone	-	
metformin vs Vildagliptin			
Schweizer , 2007 n=254/526 follow-up: 52	2.000 versus Vildagliptin	-	
metformin vs Glipizide			
Campbell , 1994 n=24/24 follow-up: 52	1.000 versus Glipizide	-	
Stakos vs glipizide n=59/25 follow-up: 104	500 versus Glipizide	-	
metformin vs SU/Insulin			
UKPDS (vs SU or INS) n=342/951 follow-up: 556	2.550 versus SU/Insulin	Type 2 diabetic patients	Parallel groups open UK

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Yki-Yarvinen vs glibenclamide, 1999:

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Yki-Yarvinen vs insulin, :

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Maji vs control, 2005:

Maji D, Roy RU, Das S Prevention of type 2 diabetes in the prediabetic population. *J Indian Med Assoc* 2005;103:609-11 [[16570766](#)]

UKPDS 34 vs control, :**UKPDS 34 bis, :****Zhang, :**

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2 PPAR modulator

Trial	Treatments	Patients	Trials design and methods
tesaglitazar vs			
GALLANT 9 [NCT00242372] n=NA	-	-	
GALLANT 7 [NCT00251940] n=NA	-	-	
GALLANT 8 [NCT00251953] n=NA	-	-	
GALLANT 6 [NCT00214565] n=NA	-	-	
D6160C00028 [NCT00255541] n=NA	-	-	
D6160C00026 [NCT00252772] n=NA	-	-	
GALLANT 14 [NCT00261352] n=NA	-	-	
D6160C00055 [NCT00252837] n=NA	-	-	
D6160C00040 [NCT00229684] n=NA	-	-	

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Trial	Treatments	Patients	Trials design and methods
aleglitazar vs actos			
BC20265 <i>ongoing</i> [NCT00461058] n=NA follow-up:	aleglitazar versus Actos(r)	-	USA
aleglitazar vs placebo			
ALECARDIO [NCT01042769] n=NA	-	-	
BC22140 <i>ongoing</i> [NCT01042769] n=NA follow-up: 2.5 years	aleglitazar on top of standard care versus placebo	patients with recent acute coronary syndrome (ACS) and type 2 diabetes mellitus	double-blind USA

References

GALLANT 9, :
GALLANT 7, :
GALLANT 8, :
GALLANT 6, :
D6160C00028, :
D6160C00026, :
GALLANT 14, :
D6160C00055, :
D6160C00040, :
BC20265, 0:
ALECARDIO, :
BC22140, 0:

3 thiazolidinediones

Trial	Treatments	Patients	Trials design and methods
vs			
Bailey , 2005 n=NA	-	-	
EMPIRE (Weissman) , 2005 n=NA	-	-	
Hallsten , 2002 n=NA	-	-	
Hanefeld , 2004 n=NA	-	-	

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Trial	Treatments	Patients	Trials design and methods
Lawrence , 2004 n=NA	-	-	
Pavo , 2003 n=NA	-	-	
Ramachandran , 2004 n=NA	-	-	
Scherthamer , 2004 n=NA	-	-	
Yamanouchi , 2005 n=NA	-	-	
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
vs DPP-4 inhibitor (add on to metformin)			
Scott (vs DPP-4 inhibitor) , 2008 n=87/94 follow-up: 18 weeks	-	-	
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

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Trial	Treatments	Patients	Trials design and methods
49653/097 n=122/120 follow-up: 156 wk	Rosiglitazone versus Glyburide	patients with type 2 diabetesDM	Parallel groups
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
pioglitazone vs metformin			
EC404 n=597/597 follow-up: 52 wk	Pioglitazone versus 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
pioglitazone + sulfonylurea vs metformin + sulfonylurea			
EC409 n=319/320 follow-up: 104 wk	Pioglitazone + sulfonylurea versus Metformin + sulfonylurea	patients with type 2 diabetes	Parallel groups
pioglitazone vs placebo			
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
rosiglitazone vs placebo			

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Trial	Treatments	Patients	Trials design and methods
49653/011 n=357/176 follow-up: 24 wk	Rosiglitazone versus Placebo	patients with type 2 diabetes	Parallel groups
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
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 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
rosiglitazone vs placebo (add on gliclazide)			
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)			

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Trial	Treatments	Patients	Trials design and methods
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 diabetes poorly controlled on Gly	Parallel groups
49653/162 n=168/172 follow-up: 26 wk	Rosiglitazone and glyburide versus Glyburide	patients with type 2 diabetes	Parallel groups
pioglitazone + insulin vs placebo (add on insulin)			
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
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
vs placebo (add on MET)			
Fonseca , 2000 n=113/116 follow-up: 26 weeks	-	-	
Gomez-Perez , 2002 n=36/34 follow-up: 26 weeks	-	-	
scott , 2008 n=87/91 follow-up: 18 weeks	-	-	
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
rosiglitazone vs placebo (add on MET)			

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Trial	Treatments	Patients	Trials design and methods
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
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
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 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			
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

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Trial	Treatments	Patients	Trials design and methods
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
vs sulfonylurea (add on to MET)			
Garber , 2006 n=155/159 follow-up: 24 weeks	-	-	
Hamann , 2008 n=294/301 follow-up: 52 weeks	-	-	
Khanolkar , 2008 n=25/25 follow-up: 24 weeks	-	-	
Matthews , 2005 n=317/313 follow-up: 52 weeks	-	-	
pioglitazone + metformin vs sulfonylurea + metformin			
EC410 n=317/313 follow-up: 104 wk	Pioglitazone + metformin versus Sulfonylurea + metformin	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
pioglitazone vs vildagliptin			
Bolli , 2008 n=295/295 follow-up: 52 weeks	vildagliptin (50 mg b.i.d.) versus pioglitazone (30 mg daily)	-	
pioglitazone vs glimepiride			

continued...

Trial	Treatments	Patients	Trials design and methods
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			
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 onmonotherapy with either metformin or sulfonylurea andin less than optimal blood glucose control (HbA1c >7090%)	Parallel groups open Europe, Australia

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4 About TrialResults-center.org

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