

Clinical trials of metformin

TrialResults-center www.trialresultscenter.org

1 diabetes type 2

Trial	Treatments	Patients	Trials design and methods
metformin vs Acarbose			
Maji vs acarbose n=48/48 follow-up: 156	500 versus Acarbose	-	
lifestyle modification + metformin vs control			
IDDP (Ramachandran) , 2006 n=531 follow-up: 2.5 y	advice on lifestyle modification, metformin, or both versus given standard health care advice (control)	native Asian Indians with impaired glucose tolerance	Parallel groups open India
Jarret , 1979 n=204 follow-up: 4.3 y	carbohydrate restriction with phenformin 50 mg daily versus carbohydrate restriction alone	men with impaired glucose toleranc	Parallel groups open
metformin vs control			
James , 2005 n=10/10 follow-up: 8 weeks	metformin 1 g BID versus no treatment	Abdominal obesity with insulin resistance[
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	-	

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Trial	Treatments	Patients	Trials design and methods
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	-	
nateglinide + metformin vs metformin			
Horton DOUBLON , 2000 n=172/178 follow-up: 24 weeks	nateglinide (120 mg, ac) and metformin (500 mg, tid) versus 500 mg metformin three times a day	-	
repaglinide + metformin vs metformin			
AGEE-1411 [NCT01465152] n=NA follow-up:	-	-	open Spain
saxagliptin plus metformin XR 1500mg vs metformin up to 2000mg			
CV181-085 [NCT00918138] n=NA follow-up:	Saxagliptin in Combination With Metformin XR 1500 mg versus Up-titrated Metformin XR to 2000 mg	Subjects With Type 2 Diabetes Who Have Inadequate Glycemic Control With Diet and Exercise and a Stable Dose of Metformin XR 1500 mg	
metformin vs None			
Vahatalo vs control , 2007 n=26/11 follow-up: 52	2.500 versus None	-	
Maji vs control , 2005 n=48/90 follow-up: 156	500 versus None	-	

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Trial	Treatments	Patients	Trials design and methods
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	-	
BIAsp 30)twice-daily + metformin vs once-daily glargine + metformin + secretagogues			
Ligthelm , 2011 n=NA follow-up: 24 weeks	biphasic insulin aspart 70/30 (BIAsp 30)twice-daily + metformin versus once-daily glargine + metformin + secretagogues	type 2 diabetic patients who were not maintaining glycemic control on basal insulin and oral antidiabetic drugs	Parallel groups open-label
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			
Baillargeon , 2004 n=32/32 follow-up: 26 weeks	metformin 850 mg BID versus placebo	Non obese women with PCOS	

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Trial	Treatments	Patients	Trials design and methods
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
Bridger , 2006 n=11/11 follow-up: 12 weeks	metformin 750 mg BID versus placebo	Adolescents with PCOS and insulin resistance	
Charles , 1998 n=227/230 follow-up: 52 weeks	metformin 850 mg BID versus placebo	Abdominal obesity	
Charles , 2000 n=83/85 follow-up: 13 weeks	metformin 850 mg BID versus placebo	Abdominal obesity, hypertension, and elevated triglycerides	
Choux , 2003 n=15/17 follow-up: 13 weeks	metformin 500 mg TID versus placebo	PCO	
Crave , 1995 n=12/12 follow-up: 17 weeks	metformin 850 mg BID versus placebo	Overweight with PCO	
EDIT (Holman) , 2003 n=631 follow-up:	metformin 500 mg three times/day, versus placebo	(WHO 1985 criteria)	UK
Douek , 2005 n=92/91 follow-up: 52	2.000 versus Placebo	-	
HOME , 2009 [NCT00375388] n=196/194 follow-up: 4.3 y	metformin 850 mg versus placebo	patients with DM2 treated with insulin	Parallel groups double-blind The Netherlands
Fleming , 2002 n=45/47 follow-up: 17 weeks	metformin 850 mg BID versus placebo	PCO	
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
Freemark , 2001 n=16/16 follow-up: 26 weeks	metformin 500 mg BID versus placebo	Insulin resistance and family history of diabetes	
Gambineri , 2004 n=10/10 follow-up: 26 weeks	metformin 850 mg BID versus placebo	Obesity and PCOS	
Giugliano , 1993 n=12/12 follow-up: 12 weeks	metformin 850 mg BID versus placebo	Hypertension with normal glucose tolerance	
Hoeger , 2004 n=18/20 follow-up: 48 weeks	metformin 850 mg BID + lifestyle modification versus placebo + lifestyle modification	Overweight with PCOS[
Kooy (HOME) , 2009 n=196/194 follow-up: 220	2.000 versus Placebo	Patients with type 2 diabetes	Parallel groups double blind
Kay , 2001 n=12/12 follow-up: 8 weeks	metformin 850 mg BID versus placebo	Adolescents with morbid obesity	
Kelly , 2002 n=16/16 follow-up: 26 weeks	metformin 500 mg TID versus placebo	PCO	
Kocak , 2002 n=28/28 follow-up: 8 weeks	metformin 850 mg BID versus placebo	PCO	
Lehtovirta , 2001 n=20/20 follow-up: 26 weeks	metformin 500 mg BID versus placebo	Overweight with impaired glucose tolerance and family history of diabetes	
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	-	

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Trial	Treatments	Patients	Trials design and methods
Li , 1999 n=33/37 follow-up: 12 months	metformin 250 mg three times/day versus placebo	patients with impaired glucose tolerance (WHO 1985 criteria)	Parallel groups double blind China
Li n=33/37 follow-up: 52	2.000 versus Placebo	-	
Moggetti , 2000 n=12/11 follow-up: 26 weeks	metformin 500 mg TID versus placebo	PCOS with normal glucose tolerance	
Martinez n=35/73 follow-up: 52	1.700 versus Placebo	-	
Morel , 1999 n=19/19 follow-up: 8 weeks	metformin 850 mg BID versus placebo	Impaired glucose tolerance	
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	-	
Ng , 2001 n=10/10 follow-up: 12 weeks	metformin 500 mg TID versus placebo	PCO	
Orchard , 2005 n=1073/1082 follow-up: 156 weeks	metformin 850 mg BID versus placebo	Impaired glucose tolerance	
Stakos vs placebo n=59/97 follow-up: 104	500 versus Placebo	-	
Shuster n=45/81 follow-up: 104	500 versus Placebo	-	

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Trial	Treatments	Patients	Trials design and methods
Pasquali , 2000 n=20/20 follow-up: 26 weeks	metformin 850 mg BID versus placebo	Abdominal obesity with and without PCO	
DPP (Knowler) n=1073/1082 follow-up: 156	1.700 versus Placebo	-	
Ibanez 62 n=19/19 follow-up: 208	425 versus Placebo	-	
Rodriguez , 2004 n=10/11 follow-up: 20 weeks	metformin 1.7 g/d versus placebo	Obesity with insulin resistance	
Rodriguez-Moctezuma , 2004 n=12/11 follow-up: 8 weeks	metformin 850 mg BID versus placebo	Family history of diabetes	
Sirtori , 1984 n=15/15 follow-up: 26 weeks	metformin 850 mg BID versus placebo	Peripheral vascular disease	
Srinivasan , 2006 n=28/28 follow-up: 26 weeks	metformin 1 g BID versus placebo	Children and adolescents with obesity and insulin resistance	
Stakos , 2005 n=59/97 follow-up: 104 weeks	metformin 500 mg/d versus placebo	African-Americans with insulin resistance and family history of diabetes	
Sturrock , 2002 n=17/17 follow-up: 13 weeks	metformin 1500 mg/d versus placebo	PCO	
Tang , 2006 n=69/74 follow-up: 26 weeks	metformin 850 mg BID versus placebo	Obesity with PCO	
US-DPP (metformin) (Knowler) , 2002 n=3234 follow-up: 2.8 years	metformin 850mg twice daily versus placebo	nondiabetic patients with elevated glucose and high risk for diabetes	Parallel groups double blind USA
Vitale , 2005 n=32/33 follow-up: 13 weeks	metformin 500 mg BID versus placebo	Metabolic syndrome	
rosiglitazone and metformin vs placebo			

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Trial	Treatments	Patients	Trials design and methods
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
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
metformin + repaglinide vs repaglinide			
AGEE-1411 [NCT01465152] n=NA follow-up: 24 weeks	metformin and repaglinide versus repaglinide	subjects with type 2 diabetes in which diet and exercise have failed	open Spain
repaglinide + metformin vs repaglinide			
AGEE-3705 [NCT00819741] n=NA follow-up:	repaglinide plus metformin versus repaglinide alone	Chinese subjects with type 2 diabetes having an HbA1c (glycosylated haemoglobin A1c) over 8.5 % and who never have taken oral sugar-lowering drugs before	open China
AGEE-3018 n=NA follow-up:	-	-	
metformin vs Rosiglitazone			
maji vs rosiglitazone n=48/48 follow-up: 156	500 versus Rosiglitazone	-	
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	-	
repaglinide + metformin vs rosiglitazone + metformin			

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Trial	Treatments	Patients	Trials design and methods
Raskin , 2009 [NCT00399711] n=NA follow-up: 26 weeks	repaglinide and metformin fixed dose combination tablet given as twice daily versus twice daily rosiglitazone and metformin fixed dose combination	subjects with type 2 diabetes currently on monotherapy	open USA
repaglinide + metformin vs SU or MET			
AGEE-3017 [NCT00568984] n=NA follow-up:	combination therapy of repaglinide and metformin versus conventional treatment with a sulphonylurea or metformin in monotherapy	-	China
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
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 glyburide			
ADOPT , 2006 [NCT00279045] n=1454/1441 follow-up: 4 years (median)	metformin, versus glyburide	recently diagnosed type 2 diabetes	Parallel groups
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

More details and results :

- antidiabetic drugs for diabetes type 2 in all types of patients at <http://www.trialresultscenter.org/go-Q81>
- 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 sensitizer for diabetes type 2 in all type of patients at <http://www.trialresultscenter.org/go-Q377>
- insulin secretagogues for diabetes type 2 in all type of patients at <http://www.trialresultscenter.org/go-Q409>
- prevention for diabetes type 2 in people with impaired glucose tolerance at <http://www.trialresultscenter.org/go-Q416>
- insulin therapy for diabetes type 2 in all type of patients at <http://www.trialresultscenter.org/go-Q548>
- insulin secretagogues - Meglitinides (glinides) for diabetes type 2 in all types of patients at <http://www.trialresultscenter.org/go-Q549>
- insulin secretagogues - DPP-4 inhibitors for diabetes type 2 in all types of patients at <http://www.trialresultscenter.org/go-Q550>
- insulin sensitizer - biguanides for diabetes type 2 in all type of patients at <http://www.trialresultscenter.org/go-Q551>
- 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>

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2 impaired fasting glucose

17

Trial	Treatments	Patients	Trials design and methods
metformin vs placebo			
US-DPP (metformin) (Knowler) , 2002 n=3234 follow-up: 2.8 years	metformin 850mg twice daily versus placebo	nondiabetic patients with elevated glucose and high risk for diabetes	Parallel groups double blind USA
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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