

Clinical trials of antidiabetic drugs for diabetes type 2 in patients inadequately controlled on metformin

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1 albiglutide

Trial	Treatments	Patients	Trials design and methods
albiglutide weekly vs placebo (add on MET)			
Rosenstock (30 mg weekly) , 2009 [NCT00518115] n=31/52 follow-up: 16 weeks	albiglutide 30mg weekly versus placebo	patients with type 2 diabetes inadequately controlled with diet and exercise or metformin monotherapy	Parallel groups double-blind US, Mexico, Chile, Dominical republic

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Rosenstock (30 mg weekly), 2009:

Rosenstock J, Reusch J, Bush M, Yang F, Stewart M, , Potential of albiglutide, a long-acting GLP-1 receptor agonist, in type 2 diabetes: a randomized controlled trial exploring weekly, biweekly, and monthly dosing. *Diabetes Care* 2009;32:1880-6. [[19592625](#)] [10.2337/dc09-0366](#)

2 bitherapy with MET

Trial	Treatments	Patients	Trials design and methods
dapagliflozin vs placebo (add on MET)			
Bailey (MB102014) , 2010 [NCT00528879] n=NA follow-up: 24 weeks	dapagliflozin (25 mg, n=137; 5 mg, n=137; or 10 mg, n=135) versus placebo	adults with type 2 diabetes who were receiving daily metformin (1500 mg per day) and had inadequate glycaemic control	Parallel groups double-blind

References

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Bailey CJ, Gross JL, Hennicken D, Iqbal N, Mansfield TA, List JF Dapagliflozin add-on to metformin in type 2 diabetes inadequately controlled with metformin: a randomized, double-blind, placebo-controlled 102-week trial. *BMC Med* 2013;11:43 [[23425012](#)]

3 DPP-4 inhibitors

Trial	Treatments	Patients	Trials design and methods
linagliptin low dose vs linagliptin			
linagliptin 1218.62 <i>ongoing</i> [NCT01012037] n=NA follow-up: 12 weeks	linagliptin low dose 2.5 mg twice daily versus linagliptin medium dose 5 mg once daily	patients with type 2 diabetes mellitus with insufficient glycaemic control with metformin	double-blind Belgium

References

linagliptin 1218.62, 0:

4 DPP-4 inhibitors add on MET

Trial	Treatments	Patients	Trials design and methods
linagliptin vs glimepiride (add on MET)			
Gallwitz , 2012 [NCT00622284] n=777/775 follow-up: 104 weeks	linagliptin (5 mg once daily) add-on therapy to preferably >1500 mg metformin versus glimepiride (14 mg) orally once daily add-on therapy to preferably >1500 mg metformin	type 2 diabetes mellitus with insufficient glycaemic control with metformin	Parallel groups double-blind USA
alogliptin vs placebo (add on MET)			
Nauck , 2009 [NCT00286442] n=210/104 follow-up: 26 weeks	alogliptin 12.5 and 25 mg once daily versus placebo	patients whose HbA(1c) levels were inadequately controlled on metformin alone	Parallel groups double-blind
linagliptin vs placebo (add on MET)			
linagliptin 1218.65 <i>ongoing</i> [NCT01215097] n=NA follow-up: 24 weeks	5 mg of Linagliptin administered orally once daily versus placebo (on top metformin)	patients with type 2 diabetes and insufficient glycaemic control with metformin	parallel groups double-blind China
saxagliptin vs placebo (add on MET)			
CV181-080 [NCT00885378] n=NA follow-up:	2.5 mg Saxagliptin, Twice Daily versus placebo	Subjects With Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control on Metformin IR Alone	
DeFronzo , 2009 [NCT00121667] n=191/179 follow-up: 24 weeks	saxagliptin (2.5, 5, or 10 mg once daily) versus placebo	Patients With Inadequately Controlled Type 2 Diabetes With Metformin Alone	
sitagliptin vs placebo (add on MET)			

continued...

Trial	Treatments	Patients	Trials design and methods
Charbonnel , 2006 [NCT0086515] n=NA follow-up:	sitagliptin 100 mg daily (add-on to metformin therapy) versus placebo (add-on to metformin therapy);	-	
Nauck , 2007 [NCT00094770] n=NA follow-up:	sitagliptin 100 mg daily (add-on to metformin therapy) versus placebo (add-on to metformin therapy);	-	
Scott** (sit vs pbo on top met) , 2007 n=NA follow-up:	sitagliptin 100 mg daily (add-on to metformin therapy) versus placebo (add-on to metformin therapy).	patients with type 2 diabetes who were inadequately on MET monotherapy	
vildagliptin vs placebo (add on MET)			
Ahren , 2004 n=56/51 follow-up: 12 weeks	vildagliptin 50 mg daily (add-on to metformin therapy) versus placebo (add-on to metformin therapy)	patients with type 2 diabetes	double-blind
Bosi , 2007 [NCT00099892] n=185/182 follow-up:	vildagliptin (50 or) 100 mg daily (add-on to metformin therapy) versus placebo (add-on to metformin therapy)	patients with type 2 diabetes inadequately controlled with metformin	double-blind
Goodman , 2009 n=125/122 follow-up: 24 weeks	vildagliptin 100 mg given in the morning, vildagliptin 100 mg given in the evening versus placebo	patients inadequately controlled with metformin	Parallel groups double-blind
saxagliptin vs sitagliptin (add on MET)			
saxagliptin vs sitagliptin n=403/398 follow-up: 18 weeks	saxagliptin 5 mg once daily add on metformin versus sitagliptin 100 mg once daily add on metformin	adults with type 2 diabetes who did not attain adequate glycemic control on metformin therapy alone	Parallel groups
vildagliptin vs Sulfonylurea (add on to MET)			
Ferrannini , 2009 [NCT00106340] n=1396/1393 follow-up: 52 weeks	vildagliptin 50 mg twice daily versus glimepiride titrated up to 6 mg/day	Patients inadequately controlled on metformin monotherapy (HbA(1c) 6.5-8.5%)	Parallel groups double-blind
vildagliptin vs pioglitazone (add on MET)			
Bolli , 2008 [NCT00237237] n=295/281 follow-up:	vildagliptin 100 mg daily (add-on to metformin therapy) versus pioglitazone 30 mg daily (add-on to metformin therapy)	patients with type 2 diabetes inadequately controlled with metformin monotherapy	double-blind

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with type 2 diabetes inadequately controlled on metformin: a randomised, double-blind, non-inferiority trial. *Lancet* 2012 Aug 4;380:475-83 [22748821] [10.1016/S0140-6736\(12\)60691-6](#)

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5 glucagon-like peptide analogs

Trial	Treatments	Patients	Trials design and methods
liraglutide other doses vs placebo			
NN2211-1799 <i>ongoing</i> [NCT00620282] n=NA follow-up: 3 months	liraglutide Stepwise dose increase, s.c. injection, once daily versus placebo	subjects with type 2 diabetes who are on diet and lifestyle changes or treated with metformin alon	double-blind USA
tasoglutide vs placebo			
BC21713 (vs placebo) <i>ongoing</i> [NCT00754988] n=NA follow-up:	tasoglutide (10mg once weekly or 10mg once weekly for 4 weeks followed by 20mg once weekly), versus placebo or sitagliptin 100mg once daily in addition to their continued prestudy metformin treatment	patients with type 2 diabetes mellitus inadequately controlled with metformin	parallel groups double-blind USA
tasoglutide 10mg once weekly vs placebo			
Nauck 10 once weekly vs PBO , 2009 [NCT00423501] n=257/49 follow-up: 12 weeks	tasoglutide, either 5, 10, or 20 mg once weekly or 10 or 20 mg once every 2 weeks for 8 weeks versus placebo	patients with type 2 diabetes inadequately controlled with metformin	Parallel groups double-blind
exenatide 10g/d vs placebo (add on MET)			
DeFronzo 10g/d , 2005 [NCT00039013] n=110/113 follow-up: 30 weeks	Exenatide 1020 g daily versus Placebo on-top of Metformin	patients with type 2 diabetes failing to achieve glycemic control with maximally effective metformin doses	Parallel groups double blind USA
exenatide 20g/d vs placebo (add on MET)			
DeFronzo 20g/d , 2005 [NCT00039013] n=NA follow-up: 30 weeks	Exenatide 1020 g daily versus Placebo on-top of Metformin	patients with type 2 diabetes failing to achieve glycemic control with maximally effective metformin doses	Parallel groups double blind USA
exenatide weekly vs placebo (add on MET)			
Kim , 2007 [NCT00103935] n=30/15 follow-up: 15 weeks	exenatide LAR 0.8 or 2 g daily versus Placebo on-top of metformin	subjects with type 2 diabetes suboptimally controlled with metformin and/or diet and exercise	Parallel groups double blind
liraglutide 1.8mg vs placebo (add on MET)			

continued...

Trial	Treatments	Patients	Trials design and methods
LEAD-2 (Nauck) (1.8mg vs placebo) , 2009 [NCT00318461] n=242/122 follow-up: 26 weeks	Liraglutide 1.8 mg daily versus Placebo on-top of Metformin	subjects previously treated with oral antidiabetes therapy	Parallel groups double blind 21 countries
tasoglutide vs placebo (add on MET)			
Ratner (20mg once weekly) , 2010 [NCT00460941] n=97/32 follow-up: 8 weeks (+4wk)	tasoglutide s.c. 20mg once weekly for 8 weeks versus placebo s.c. once weekly on top metformin	subjects with Type 2 diabetes inadequately controlled on metformin alone	Parallel groups double-blind Australia, France, Germany, Mexico, Peru, USA
BC22092 ongoing [NCT00823992] n=NA follow-up:	tasoglutide (10mg sc once weekly for 4 weeks followed by 20mg once weekly) in addition to their prescribed, pre-existing metformin therapy versus placebo	obese patients with type 2 diabetes mellitus inadequately controlled with metformin monotherapy	parallel groups double-blind USA
exenatide 20g/d vs placebo (add on MET+/-SU)			
Gao , 2009 [NCT00324363] n=234/232 follow-up: 16 weeks	exenatide 5 mg then 10 mg twice-daily for 4 and 12 weeks versus placebo	Asian descent with type 2 diabetes and inadequate glycemic control taking metformin alone or Met and sulfonylureas	Parallel groups double-blind 4 countries
liraglutide other doses vs sitagliptin (add on MET)			
MK-0431-403 ongoing [NCT01296412] n=NA follow-up:	Liraglutide + metformin versus Sitagliptin + metformin	patients with Type 2 Diabetes that is not adequately controlled with metformin alone	parallel groups open
liraglutide 1.8mg vs glimepiride (add on MET)			
LEAD-2 (Nauck) (1.8 mg vs glimepiride) , 2009 [NCT00318461] n=242/244 follow-up: 26 weeks	Liraglutide 1.8 mg daily for 26 weeks versus Glimepiride on-top of Metformin	patients with type 3 diabetes previously treated with oral antidiabetes (OAD) therap	Parallel groups double blind 21 countries
liraglutide 1.2mg vs sitagliptin			
Pratley 1.2mg , 2010 [NCT00700817] n=225/219 follow-up: 26 weeks	liraglutide 1.2mg subcutaneously once daily versus oral sitagliptin 100mg once daily	patients with type 2 diabetes who did not have adequate glycemic control with metformin	Parallel groups open Europe, USA, Canada
liraglutide 1.8mg vs sitagliptin			
Pratley 1.8mg , 2010 [NCT00700817] n=221/219 follow-up: 26 weeks	liraglutide 1.8mg subcutaneously once daily versus oral sitagliptin 100mg once daily	patients with type 2 diabetes who did not have adequate glycemic control with metformin	Parallel groups open Europe, USA, Canada

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BC21713 (vs placebo), 0:

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Ratner R, Nauck M, Kapitzka C, Asnagli V, Boldrin M, Balena R, Safety and tolerability of high doses of taspoglutide, a once-weekly human GLP-1 analogue, in diabetic patients treated with metformin: a randomized double-blind placebo-controlled study. *Diabet Med* 2010;27:556-62. [[20536952](#)] [10.1111/j.1464-5491.2010.02990.x](#)

BC22092, 0:

Gao, 2009:

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MK-0431-403, 0:

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6 lixisenatide

Trial	Treatments	Patients	Trials design and methods
lixisenatide vs placebo (add on MET)			
Ratner DRI6012 , 2010 [NCT00299871] n=433/109 follow-up: 13 weeks	subcutaneous lixisenatide doses of 5, 10, 20 or 30 microg once daily or twice daily versus placebo	patients with Type 2 diabetes inadequately controlled with metformin (≥ 1000 mg/day)	Parallel groups double-blind (nature not volume) multinational
GETGOAL-M ongoing [NCT00712673] n=NA follow-up: 24 weeks	-	Type 2 diabetes mellitus insufficiently controlled with metformin	Parallel groups double-blind USA
lixisenatide vs sitagliptin (add on MET)			
EFC10780 , 2010 ongoing [NCT00976937] n=NA follow-up: 24 weeks	Lixisenatide titrated 15-20 g once daily versus Sitagliptin (add-on to Metformin)	Obese Type 2 Diabetic Patients Younger Than 50	Parallel groups double-blind WW

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References

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GETGOAL-M, 0:

EFC10780, 2010:

7 meglitinides (glinides)

Trial	Treatments	Patients	Trials design and methods
repaglinide vs control (add on MET)			
Moses , 1999 n=27/27 follow-up: 12 weeks	prestudy dose of metformin with the addition of repaglinide versus prestudy dose of metformin	patients with type 2 diabetes who had inadequate glycemic control (HbA1c $>7.1\%$) when receiving the antidiabetic agent metformin	Parallel groups open
nateglinide vs gliclazide (add on MET)			
Ristic , 2006 n=133/129 follow-up: 24 weeks	nateglinide plus metformin versus gliclazide plus metformin	Patients with inadequate glucose control on maximal doses of metformin	Parallel groups double-blind

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Moses R, Slobodniuk R, Boyages S, Colagiuri S, Kidson W, Carter J, Donnelly T, Moffitt P, Hopkins H Effect of repaglinide addition to metformin monotherapy on glycemic control in patients with type 2 diabetes. *Diabetes Care* 1999;22:119-24 [[10333912](#)]

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Ristic S, Collober-Maugeais C, Cressier F, Tang P, Pecher E Nateglinide or gliclazide in combination with metformin for treatment of patients with type 2 diabetes mellitus inadequately controlled on maximum doses of metformin alone: 1-year trial results. *Diabetes Obes Metab* 2007;9:506-11 [[17587393](#)] [10.1111/j.1463-1326.2006.00632.x](#)

8 sulfonylureas G3 add on MET

Trial	Treatments	Patients	Trials design and methods
glimepiride vs placebo (add on MET)			
Charpentier , 2001 n=NA follow-up:	metformin and glimepiride versus metformin	Type 2 diabetic patients aged 35-70 years inadequately controlled by metformin monotherapy 2550 mg daily	double-blind France

References

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9 About TrialResults-center.org

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