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

References

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

Bailey (MB102014), 2010:

Bailey CJ, Gross JL, Pieters A, Bastien A, List JF Effect of dapagliflozin in patients with type 2 diabetes who have inadequate glycaemic control with metformin: a randomised, double-blind, placebo-controlled trial. Lancet 2010 Jun 26;375:2223-2233 [20609968] 10.1016/S0140-6736(10)60407-2

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Kohan DE, Fioretto P, Johnsson K, Parikh S, Ptaszynska A, Ying L The effect of dapagliflozin on renal function in patients with type 2 diabetes. J Nephrol 2016;: [26894924]

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 *ongoing* [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 *ongoing* [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)j versus placebo (add-on tometformin therapy);	-	
Nauck , 2007 [NCT00094770] n=NA follow-up:	sitagliptin 100 mg daily (add-on to metformin therapy)j 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)j 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)j versus placebo (add-on to metformin therapy)mag	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)m versus placebo (add-on to metformin therapy)mag	patients with type 2 diabetes inadequately controlled with metformin	double-blind
Goodman , 2009 n=125/122 follow-up: 24 weeks	ildagliptin 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 onece 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)j	patients with type 2 diabetes inadequately controlled with metformin monotherapy	double-blind

References

Gallwitz, 2012:

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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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linagliptin 1218.65, 0:

CV181-080, :

DeFronzo, 2009:

DeFronzo RA, Hissa MN, Garber AJ, Luiz Gross J, Yuyan Duan R, Ravichandran S, Chen RS The efficacy and safety of saxagliptin when added to metformin therapy in patients with inadequately controlled type 2 diabetes with metformin alone. Diabetes Care 2009;32:1649-55 [19478198] 10.2337/dc08-1984

Karyekar C, Donovan M, Allen E, Fleming D, Ravichandran S, Chen R Efficacy and safety of saxagliptin combination therapy in US patients with type 2 diabetes. Postgrad Med 2011 Jul;123:63-70 [21680990]

Charbonnel, 2006:

Charbonnel B, Karasik A, Liu J, Wu M, Meininger G Efficacy and safety of the dipeptidyl peptidase-4 inhibitor sitagliptin added to ongoing metformin therapy in patients with type 2 diabetes inadequately controlled with metformin alone. Diabetes Care 2006;29:2638-43 [17130197] 10.2337/dc06-0706

Nauck, 2007:

Nauck MA, Meininger G, Sheng D, Terranella L, Stein PP Efficacy and safety of the dipeptidyl peptidase-4 inhibitor, sitagliptin, compared with the sulfonylurea, glipizide, in patients with type 2 diabetes inadequately controlled on metformin alone: a randomized, double-blind, non-inferiority trial. Diabetes Obes Metab 2007;9:194-205 [17300595] 10.1111/j.1463-1326.2006.00704.x

Seck TL, Engel SS, Williams-Herman DE, Sisk CM, Golm GT, Wang H, Kaufman KD, Goldstein BJ Sitagliptin more effectively achieves a composite endpoint for A1C reduction, lack of hypoglycemia and no body weight gain compared with glipizide. Diabetes Res Clin Pract 2011;93:e15-7 [21477878] 10.1016/j.diabres.2011.03.006

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Scott (sit vs pbo on top met), 2007:**

Scott R, Loeys T, Davies MJ, Engel SS Efficacy and safety of sitagliptin when added to ongoing metformin therapy in patients with type 2 diabetes. Diabetes Obes Metab 2008;10:959-69 [18201203] 10.1111/j.1463-1326.2007.00839.x

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Ahrn B, Gomis R, Standl E, Mills D, Schweizer A Twelve- and 52-week efficacy of the dipeptidyl peptidase IV inhibitor LAF237 in metformin-treated patients with type 2 diabetes. Diabetes Care 2004;27:2874-80 [15562200]

Bosi, 2007:

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Bolli, 2008:

Bolli G, Dotta F, Rochotte E, Cohen SE Efficacy and tolerability of vildagliptin vs. pioglitazone when added to metformin: a 24-week, randomized, double-blind study. Diabetes Obes Metab 2008;10:82-90 [18034842] 10.1111/j.1463-1326.2007.00820.x

Bolli G, Dotta F, Colin L, Minic B, Goodman M Comparison of vildagliptin and pioglitazone in patients with type 2 diabetes inadequately controlled with metformin. Diabetes Obes Metab 2009 Jun;11:589-95 [19515179] 10.1111/j.1463-1326.2008.01023.x

5 glucagon-like peptide analogs

Trial	Treatments	Patients	Trials design and methods
liraglutide other doses vs placebo			
NN2211-1799 *ongoing* [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
taspoglutide vs placebo			
BC21713 (vs placebo) *ongoing* [NCT00754988] n=NA follow-up:	taspoglutide (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
taspoglutide 10mg once weekly vs placebo			
Nauck 10 once weekly vs PBO , 2009 [NCT00423501] n=257/49 follow-up: 12 weeks	taspoglutide, 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
taspoglutide vs placebo (add on MET)			
Ratner (20mg once weekly) , 2010 [NCT00460941] n=97/32 follow-up: 8 weeks (+4wk)	taspoglutide 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:	taspoglutide (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 desccent 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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NN2211-1799, 0:

BC21713 (vs placebo), 0:

Nauck 10 once weekly vs PBO, 2009:

Nauck MA, Ratner RE, Kapitza C, Berria R, Boldrin M, Balena R, Treatment with the human once-weekly glucagon-like peptide-1 analog taspoglutide in combination with metformin improves glycemic control and lowers body weight in patients with type 2 diabetes inadequately controlled with metformin alone: a double-blind placebo-controlled study. Diabetes Care 2009;32:1237-43. [19366970] 10.2337/dc08-1961

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Blonde L, Klein EJ, Han J, Zhang B, Mac SM, Poon TH, Taylor KL, Trautmann ME, Kim DD, Kendall DM Interim analysis of the effects of exenatide treatment on A1C, weight and cardiovascular risk factors over 82 weeks in 314 overweight patients with type 2 diabetes. Diabetes Obes Metab 2006;8:436-47 [16776751] 10.1111/j.1463-1326.2006.00602.x

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DeFronzo 20g/d, 2005:

DeFronzo RA, Ratner RE, Han J, Kim DD, Fineman MS, Baron AD Effects of exenatide (exendin-4) on glycemic control and weight over 30 weeks in metformin-treated patients with type 2 diabetes. Diabetes Care 2005;28:1092-100 [15855572]

Kim, 2007:

Kim D, MacConell L, Zhuang D, Kothare PA, Trautmann M, Fineman M, Taylor K Effects of once-weekly dosing of a long-acting release formulation of exenatide on glucose control and body weight in subjects with type 2 diabetes. Diabetes Care 2007;30:1487-93 [17353504] 10.2337/dc06-2375

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Ratner R, Nauck M, Kapitza C, Asnaghi 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:

Gao Y, Yoon KH, Chuang LM, Mohan V, Ning G, Shah S, Jang HC, Wu TJ, Johns D, Northrup J, Brodows R Efficacy and safety of exenatide in patients of Asian descent with type 2 diabetes inadequately controlled with metformin or metformin and a sulphonylurea. Diabetes Res Clin Pract 2009;83:69-76 [19019476] 10.1016/j.diabres.2008.09.037

MK-0431-403, 0:

LEAD-2 (Nauck) (1.8 mg vs glimepiride), 2009:

Nauck M, Frid A, Hermansen K, Shah NS, Tankova T, Mitha IH, Zdravkovic M, Dring M, Matthews DR Efficacy and safety comparison of liraglutide, glimepiride, and placebo, all in combination with metformin, in type 2 diabetes: the LEAD (liraglutide effect and action in diabetes)-2 study. Diabetes Care 2009;32:84-90 [18931095] 10.2337/dc08-1355

Pratley 1.2mg, 2010:

Pratley RE, Nauck M, Bailey T, Montanya E, Cuddihy R, Filetti S, Thomsen AB, Sndergaard RE, Davies M Liraglutide versus sitagliptin for patients with type 2 diabetes who did not have adequate glycaemic control with metformin: a 26-week, randomised, parallel-group, open-label trial. Lancet 2010 Apr 24;375:1447-1456 [20417856] 10.1016/S0140-6736(10)60307-8

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Pratley 1.8mg, 2010:

Pratley RE, Nauck M, Bailey T, Montanya E, Cuddihy R, Filetti S, Thomsen AB, Sndergaard RE, Davies M Liraglutide versus sitagliptin for patients with type 2 diabetes who did not have adequate glycaemic control with metformin: a 26-week, randomised, parallel-group, open-label trial. Lancet 2010 Apr 24;375:1447-1456 [20417856] 10.1016/S0140-6736(10)60307-8

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

References

Ratner DRI6012, 2010:

Ratner RE, Rosenstock J, Boka G Dose-dependent effects of the once-daily GLP-1 receptor agonist lixisenatide in patients with Type 2 diabetes inadequately controlled with metformin: a randomized, double-blind, placebo-controlled trial. Diabet Med 2010;27:1024-32 [20722676] 10.1111/j.1464-5491.2010.03020.x

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

References

Moses, 1999:

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]

Moses R Repaglinide in combination therapy with metformin in Type 2 diabetes. Exp Clin Endocrinol Diabetes 1999;107 Suppl 4:S136-9 [10522839] 10.1055/s-0029-1212169

Ristic, 2006:

Ristic S, Collober-Maugeais C, Pecher E, Cressier F Comparison of nateglinide and gliclazide in combination with metformin, for treatment of patients with Type 2 diabetes mellitus inadequately controlled on maximum doses of metformin alone. Diabet Med 2006;23:757-62 [16842480] 10.1111/j.1464-5491.2006.01914.x

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

Charpentier, 2001:

Charpentier G, Fleury F, Kabir M, Vaur L, Halimi S Improved glycaemic control by addition of glimepiride to metformin monotherapy in type 2 diabetic patients. Diabet Med 2001;18:828-34 [11678974]

Charpentier G, Fleury F, Kabir M, Vaur L, Halimi S, Improved glycaemic control by addition of glimepiride to metformin monotherapy in type 2 diabetic patients. Diabet Med 2001;18:828-34. [11678974]

9 About TrialResults-center.org

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