

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](#)

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;375:2223-33. [[20609968](#)] [10.1016/S0140-6736\(10\)60407-2](#)

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 <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 |

References

Gallwitz, 2012:

Gallwitz B, Rosenstock J, Rauch T, Bhattacharya S, Patel S, von Eynatten M, Dugi KA, Woerle HJ 2-year efficacy and safety of linagliptin compared with glimepiride in patients

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](#)

Nauck, 2009:

Nauck MA, Ellis GC, Fleck PR, Wilson CA, Mekki Q Efficacy and safety of adding the dipeptidyl peptidase-4 inhibitor alogliptin to metformin therapy in patients with type 2 diabetes inadequately controlled with metformin monotherapy: a multicentre, randomised, double-blind, placebo-controlled study. *Int J Clin Pract* 2009;63:46-55 [19125992] [10.1111/j.1742-1241.2008.01933.x](#)

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](#)

Seck T, Nauck M, Sheng D, Sunga S, Davies MJ, Stein PP, Kaufman KD, Amatruda JM Safety and efficacy of treatment with sitagliptin or glipizide in patients with type 2 diabetes inadequately controlled on metformin: a 2-year study. *Int J Clin Pract* 2010;64:562-76 [20456211] [10.1111/j.1742-1241.2010.02353.x](#)

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](#)

Ahren, 2004:

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:

Bosi E, Camisasca RP, Collober C, Rochotte E, Garber AJ Effects of vildagliptin on glucose control over 24 weeks in patients with type 2 diabetes inadequately controlled with metformin. *Diabetes Care* 2007;30:890-5 [17277036] [10.2337/dc06-1732](#)

Goodman, 2009:

Goodman M, Thurston H, Penman J Efficacy and tolerability of vildagliptin in patients with type 2 diabetes inadequately controlled with metformin monotherapy. *Horm Metab Res* 2009;41:368-73 [19221978] [10.1055/s-0028-1104604](#)

saxagliptin vs sitagliptin, :

Ferrannini, 2009:

Ferrannini E, Fonseca V, Zinman B, Matthews D, Ahrn B, Byiers S, Shao Q, Dejager S Fifty-two-week efficacy and safety of vildagliptin vs. glimepiride in patients with type 2 diabetes mellitus inadequately controlled on metformin monotherapy. *Diabetes Obes Metab* 2009;11:157-66 [19125777] [10.1111/j.1463-1326.2008.00994.x](#)

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](https://doi.org/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](https://doi.org/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 <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 |

References

NN2211-1799, 0:

BC21713 (vs placebo), 0:

Nauck 10 once weekly vs PBO, 2009:

Nauck MA, Ratner RE, Kapitzka 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](#)

DeFronzo 10g/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](#)]

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](#)

Ratner RE, Maggs D, Nielsen LL, Stonehouse AH, Poon T, Zhang B, Bicsak TA, Brodows RG, Kim DD Long-term effects of exenatide therapy over 82 weeks on glycaemic control and weight in over-weight metformin-treated patients with type 2 diabetes mellitus. *Diabetes Obes Metab* 2006;8:419-28 [[16776749](#)] [10.1111/j.1463-1326.2006.00589.x](#)

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](#)

LEAD-2 (Nauck) (1.8mg vs placebo), 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](#)

Ratner (20mg once weekly), 2010:

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:

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](#)

Pratley R, Nauck M, Bailey T, Montanya E, Cuddihy R, Filetti S, Garber A, Thomsen AB, Hartvig H, Davies M One year of liraglutide treatment offers sustained and more effective glycaemic control and weight reduction compared with sitagliptin, both in combination with metformin, in patients with type 2 diabetes: a randomised, parallel-group, open-label trial. *Int J Clin Pract* 2011;65:397-407 [[21355967](#)] [10.1111/j.1742-1241.2011.02656.x](#)

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](https://doi.org/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 |

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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 randomised, double-blind, placebo-controlled trial. *Diabet Med* 2010;27:1024-32 [20722676] [10.1111/j.1464-5491.2010.03020.x](https://doi.org/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

TrialResults-center is an innovative knowledge database that collects the results of RCTs and provides dynamic interactive systematic reviews and meta-analysis in the field of all major heart and vessels diseases.

The TrialResults-center database provides a unique view of the treatment efficacy based on all data provided directly from clinical trial results, offering a valuable alternative to personal bibliographic search, published meta-analysis, etc. Furthermore, it would allow comparing easily the various concurrent therapeutic for the same clinical condition.

Rigorous meta-analysis method is used to populate TrialResults-center: widespread search of published and non published trials, study selection using pre-specified criteria, data extraction using standard form.

TrialResults-center is continually updated on a weekly basis. We continually search all new results (whatever their publication channel) and these news results are immediately added to the database with a maximum of 1 week.

TrialResults-center is non-profit and self-funded.