

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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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 |

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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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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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MK-0431-403, 0:

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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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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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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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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

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.