

Clinical trials of antidiabetic drugs for diabetes type 2 in Patients inadequately controlled on MET+SU therapy

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1 DPP-4 inhibitors add on MET+SU

Trial	Treatments	Patients	Trials design and methods
linagliptin vs Metformin + sulfonylurea			
Owens [NCT00602472] n=NA follow-up: 24 weeks	linagliptin versus combination of metformin and an SU	type 2 diabetes mellitus with insufficient glycaemic control with metformin in combination with a sulphonylurea	Argentina

References

Owens, 0:

Owens DR, Swallow R, Woerle HJ, et al. Linagliptin improves glycemic control in Type 2 diabetes patients inadequately controlled by metformin and sulfonylurea without weight gain and low risk of hypoglycaemia. Poster no 548-P, 70th American Diabetes Association Scientific Sessions, June 2010, Orlando, Florida U.S.A.

Owens DR, Swallow R, Dugi KA, Woerle HJ Efficacy and safety of linagliptin in persons with type 2 diabetes inadequately controlled by a combination of metformin and sulphonylurea: a 24-week randomized study. Diabet Med 2011;28:1352-61 [[21781152](#)] [10.1111/j.1464-5491.2011.03387.x](#)

2 glucagon-like peptide analogs

Trial	Treatments	Patients	Trials design and methods
exenatide 10g/d vs placebo (add on SU+MET)			
Kendall 10g/d , 2005 [NCT00035984] n=245/247 follow-up: 30 weeks	Exenatide 5 g bid versus Placebo on-top of sulphonylureas+metformin	patients with type 2 diabetes unable to achieve glycemic control with metformin-sulfonylurea combination therapy	Parallel groups double blind USA
exenatide 20g/d vs placebo (add on SU+MET)			
Kendall 20g/d , 2005 [NCT00035984] n=241/247 follow-up: 30 weeks	Exenatide 10 g bid versus Placebo on-top of sulphonylureas+metformin	patients with type 2 diabetes unable to achieve glycemic control with metformin-sulfonylurea combination therapy	Parallel groups double blind USA
liraglutide 1.8mg vs placebo (add on SU+MET)			
LEAD-5 (vs placebo) , 2009 [NCT00331851] n=232/115 follow-up: 26 weeks	Liraglutide 1.8 mg daily versus Placebo on-top of sulphonylureas+metformin	adult patients with type 2 diabetes	Parallel groups double-blind 17 countries

continued...

Trial	Treatments	Patients	Trials design and methods
liraglutide 1.8mg vs exenatide on top MET/SU/MET+SU			
LEAD-6 , 2009 [NCT00518882] n=233/231 follow-up: 26 weeks	liraglutide 1.8 mg once a day versus exenatide 10 microg twice a day	Adults with inadequately controlled type 2 diabetes on maximally tolerated doses of metformin, sulphonylurea, or both	Parallel groups open 15 countries
exenatide 20g/d vs insulin (add on SU+MET)			
Heine , 2005 n=282/267 follow-up: 26 weeks	Exenatide 20 g daily versus Insulin on-top of sulphonylureas+metformin	-	open
exenatide 20g/d vs insulin BIAsp twice daily add on SU+MET			
Nauck , 2007 [NCT00082407] n=253/248 follow-up: 52 weeks	Exenatide 20 g daily versus Insulin on-top of sulphonylureas+metformin	patients with type 2 diabetes who were suboptimally controlled with sulfonylurea and metformin	Parallel groups open 13 countries
taspoglutide vs insulin glargine			
ZC22565 <i>ongoing</i> [NCT01051011] n=NA follow-up:	taspoglutide 10mg subcutaneously (sc) weekly, or taspoglutide 10mg sc weekly for 4 weeks followed by 20mg sc weekly versus insulin glargine at an initial dose of 10 international units sc daily	insulin-naive patients with type 2 diabetes mellitus inadequately controlled on merformin and sulfonylurea combination therapy	parallel groups open China
taspoglutide vs insulin glargine (add on MET)			
BC20965 <i>ongoing</i> [NCT00755287] n=NA follow-up: 2 years	taspoglutide (10 mg once weekly, or 10mg once weekly for 4 weeks followed by 20mg once weekly) versus insulin glargine (starting dose 10 IU/day) in addition to continued prestudy metformin treatment	patients with insulin-naive type 2 diabetes mellitus inadequately controlled with metformin and sulphonylurea combination therapy	open USA
liraglutide 1.8mg vs insulin glargine (add on SU+MET)			
LEAD-5 (vs Glargine) , 2009 [NCT00331851] n=232/234 follow-up: 26 weeks	Liraglutide 1.8 mg daily versus Glargine on-top of sulphonylureas+metformin	adult patients with type 2 diabetes	Parallel groups open 17 countries
taspoglutide vs pioglitazone			
BC21893 <i>ongoing</i> [NCT00909597] n=NA follow-up: 24 months	taspoglutide 10mg sc weekly, or taspoglutide 20mg sc weekly after 4 weeks of taspoglutide 10mg sc weekly versus pioglitazone 45mg/day po after 4 weeks of pioglitazone 30mg/day po	patients with type 2 diabetes mellitus inadequately controlled with sulfonylurea monotherapy or sulfonylurea plus metformin combination therapy	parallel groups double-blind USA

References

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Kendall DM, Riddle MC, Rosenstock J, Zhuang D, Kim DD, Fineman MS, Baron AD Effects of exenatide (exendin-4) on glycemic control over 30 weeks in patients with type 2

diabetes treated with metformin and a sulfonylurea. *Diabetes Care* 2005;28:1083-91 [[15855571](#)]

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LEAD-5 (vs placebo), 2009:

Russell-Jones D, Vaag A, Schmitz O, Sethi BK, Lalic N, Antic S, Zdravkovic M, Ravn GM, Sim R Liraglutide vs insulin glargine and placebo in combination with metformin and sulfonylurea therapy in type 2 diabetes mellitus (LEAD-5 met+SU): a randomised controlled trial. *Diabetologia* 2009;52:2046-55 [[19688338](#)] [10.1007/s00125-009-1472-y](#)

LEAD-6, 2009:

Buse JB, Rosenstock J, Sesti G, Schmidt WE, Montanya E, Brett JH, Zychma M, Blonde L Liraglutide once a day versus exenatide twice a day for type 2 diabetes: a 26-week randomised, parallel-group, multinational, open-label trial (LEAD-6). *Lancet* 2009 Jul 4;374:39-47 [[19515413](#)] [10.1016/S0140-6736\(09\)60659-0](#)

Buse JB, Sesti G, Schmidt WE, Montanya E, Chang CT, Xu Y, Blonde L, Rosenstock J Switching to once-daily liraglutide from twice-daily exenatide further improves glycemic control in patients with type 2 diabetes using oral agents. *Diabetes Care* 2010;33:1300-3 [[20332351](#)] [10.2337/dc09-2260](#)

Schmidt WE, Christiansen JS, Hammer M, Zychma MJ, Buse JB Patient-reported outcomes are superior in patients with Type 2 diabetes treated with liraglutide as compared with exenatide, when added to metformin, sulphonylurea or both: results from a randomized, open-label study. *Diabet Med* 2011 Mar 9; [[21388442](#)] [10.1111/j.1464-5491.2011.03276.x](#)

Heine, 2005:

Heine RJ, Van Gaal LF, Johns D, Mihm MJ, Widel MH, Brodows RG Exenatide versus insulin glargine in patients with suboptimally controlled type 2 diabetes: a randomized trial. *Ann Intern Med* 2005;143:559-69 [[16230722](#)]

Nauck, 2007:

Nauck MA, Duran S, Kim D, Johns D, Northrup J, Festa A, Brodows R, Trautmann M A comparison of twice-daily exenatide and biphasic insulin aspart in patients with type 2 diabetes who were suboptimally controlled with sulfonylurea and metformin: a non-inferiority study. *Diabetologia* 2007;50:259-67 [[17160407](#)] [10.1007/s00125-006-0510-2](#)

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BC21893, 0:

3 lixisenatide

Trial	Treatments	Patients	Trials design and methods
lixisenatide vs placebo (add on MET+/-SU)			
GetGoal-M-As <i>ongoing</i> [NCT01169779] n=NA follow-up: 24 weeks	Lixisenatide (Titration phase: 10 g maintenance phase: 20 g, add-on treatment to metformin with or without sulfonylurea versus add-on treatment to metformin with or without sulfonylurea	-	double-blind China

References

GetGoal-M-As, 0:

4 About TrialResults-center.org

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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.

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