

# 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
<b>linagliptin vs Metformin + sulfonylurea</b>			
<b>Owens</b> [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
<b>exenatide 10g/d vs placebo (add on SU+MET)</b>			
<b>Kendall 10g/d , 2005</b> [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
<b>exenatide 20g/d vs placebo (add on SU+MET)</b>			
<b>Kendall 20g/d , 2005</b> [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
<b>liraglutide 1.8mg vs placebo (add on SU+MET)</b>			
<b>LEAD-5 (vs placebo) , 2009</b> [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

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Trial	Treatments	Patients	Trials design and methods
<b>liraglutide 1.8mg vs exenatide on top MET/SU/MET+SU</b>			
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
<b>exenatide 20g/d vs insulin (add on SU+MET)</b>			
Heine , 2005 n=282/267 follow-up: 26 weeks	Exenatide 20 g daily versus Insulin on-top of sulphonylureas+metformin	-	open
<b>exenatide 20g/d vs insulin BIAsp twice daily add on SU+MET</b>			
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
<b>tasoglutide vs insulin glargine</b>			
ZC22565 <i>ongoing</i> [NCT01051011] n=NA follow-up:	tasoglutide 10mg subcutaneously (sc) weekly, or tasoglutide 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
<b>tasoglutide vs insulin glargine (add on MET)</b>			
BC20965 <i>ongoing</i> [NCT00755287] n=NA follow-up: 2 years	tasoglutide (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
<b>liraglutide 1.8mg vs insulin glargine (add on SU+MET)</b>			
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
<b>tasoglutide vs pioglitazone</b>			
BC21893 <i>ongoing</i> [NCT00909597] n=NA follow-up: 24 months	tasoglutide 10mg sc weekly, or tasoglutide 20mg sc weekly after 4 weeks of tasoglutide 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

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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

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**Nauck, 2007:**

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Sullivan SD, Alfonso-Cristancho R, Conner C, Hammer M, Blonde L Long-term outcomes in patients with type 2 diabetes receiving glimepiride combined with liraglutide or rosiglitazone. Cardiovasc Diabetol 2009 Feb 26;8:12 [19245711]

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### 3 lixisenatide

Trial	Treatments	Patients	Trials design and methods
<b>lixisenatide vs placebo (add on MET+/-SU)</b>			
<b>GetGoal-M-As</b> <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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