

# Clinical trials of antidiabetic drugs for diabetes type 2 in patients inadequately controlled with insulin

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## 1 DPP-4 inhibitors add on insulin

Trial	Treatments	Patients	Trials design and methods
<b>saxagliptin vs placebo (add on insulin)</b>			
CV181-057 [NCT00757588] n=NA follow-up:	Saxagliptin, 5 mg versus placebo (on top insulin)	Subjects With Type 2 Diabetes Who Have Inadequate Glycemic Control on Insulin Alone or on Insulin in Combination With Metformin	
<b>vildagliptin vs placebo (add on insulin)</b>			
Fonseca , 2007 [NCT00099931] n=144/152 follow-up: 24 weeks	vildagliptin 100 mg daily (add-on to insulin therapy)y versus placebo (add-on to insulin therapy)y)mag	type 2 diabetes that was inadequately controlled by insulin	double-blind

## References

CV181-057, :

Fonseca, 2007:

Fonseca V, Schweizer A, Albrecht D, Baron MA, Chang I, Dejager S Addition of vildagliptin to insulin improves glycaemic control in type 2 diabetes. Diabetologia 2007;50:1148-55 [17387446] [10.1007/s00125-007-0633-0](https://doi.org/10.1007/s00125-007-0633-0)

## 2 glucagon-like peptide analogs

Trial	Treatments	Patients	Trials design and methods
<b>exenatide 20g/d vs placebo (add on insulin)</b>			
Buse , 2011 [NCT00765817] n=138/123 follow-up: 30 weeks	twice-daily 10 g exenatide injections versus placebo (on top insulin glargine)	Adults with type 2 diabetes and an HbA1c level of 7.1% to 10.5% who were receiving insulin glargine alone or in combination with metformin or pioglitazone (or both agents)	Parallel groups double-blind Greece, Israel, Mexico, United Kingdom, USA
<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 (add on SU/MET)</b>			

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>Barnett , 2007</b> [NCT00099619] n=136/127 follow-up: 16 weeks	Exenatide 20 g daily versus Insulin	patients with type 2 diabetes	Cross over open Australia, Greece,Hungary, Italy, Mexico, and Poland
<b>Davis , 2007</b> [NCT00099333] n=33/16 follow-up: 16 weeks	Exenatide 20 g daily versus Insulin on-top of sulphonylureas/metformin	patients with type 2 diabetes using insulin in combination with oral antidiabetes agents	Parallel groups open USA
<b>exenatide 20g/d vs insulin BIAsp twice daily add on SU+MET</b>			
<b>Nauck , 2007</b> [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>exenatide weekly vs insulin glargine</b>			
<b>DURATION-3 (Diamant) , 2010</b> [NCT00641056] n=233/223 follow-up: 26 weeks	exenatide (2 mg, once-a-week injection) versus insulin glargine once-daily injection	adults with type 2 diabetes who had suboptimum glycaemic control despite use of maximum tolerated doses of blood-glucose-lowering drugs for 3 months or longer	Parallel groups open (blind analysis) USA, Puerto Rico, Europe, Russia, Australia, Korea, Taiwan, Mexico
<b>liraglutide other doses vs insulin glargine</b>			
<b>EAGLE ongoing</b> [NCT01117350] n=NA follow-up:	Liraglutide (6 mg/mL solution for injection in a 3-mL pre-filled pen (18mg)) versus Insulin Glargine (100 Units/mL solution for injection in a pre-filled SoloStar pen)	Type 2 diabetic patients failing lifestyle management and oral agents	open USA
<b>taspoglutide vs insulin glargine</b>			
<b>ZC22565 ongoing</b> [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
<b>taspoglutide vs insulin glargine (add on MET)</b>			
<b>BC20965 ongoing</b> [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
<b>exenatide other doses vs insulin glargine (add on MET/SU)</b>			
<b>Trial 8078</b> n=NA follow-up:	exenatide versus Insulin Glargine	Patients with Type 2 Diabetes Using Metformin or Sulfonylurea for Whom Insulin Is the Next Appropriate Therapy	

## References

### Buse, 2011:

Buse JB, Bergenstal RM, Glass LC, Heilmann CR, Lewis MS, Kwan AY, Hoogwerf BJ, Rosenstock J Use of twice-daily exenatide in Basal insulin-treated patients with type 2 diabetes: a randomized, controlled trial. *Ann Intern Med* 2011 Jan 18;154:103-12 [[21138825](#)] [10.1059/0003-4819-154-2-201101180-00300](#)

### 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](#)]

### Barnett, 2007:

Barnett AH, Burger J, Johns D, Brodows R, Kendall DM, Roberts A, Trautmann ME Tolerability and efficacy of exenatide and titrated insulin glargine in adult patients with type 2 diabetes previously uncontrolled with metformin or a sulfonylurea: a multinational, randomized, open-label, two-period, crossover noninferiority trial. *Clin Ther* 2007;29:2333-48 [[18158075](#)] [10.1016/j.clinthera.2007.11.006](#)

### Davis, 2007:

Davis SN, Johns D, Maggs D, Xu H, Northrup JH, Brodows RG Exploring the substitution of exenatide for insulin in patients with type 2 diabetes treated with insulin in combination with oral antidiabetes agents. *Diabetes Care* 2007;30:2767-72 [[17595353](#)] [10.2337/dc06-2532](#)

### 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](#)

### DURATION-3 (Diamant), 2010:

Diamant M, Van Gaal L, Stranks S, Northrup J, Cao D, Taylor K, Trautmann M Once weekly exenatide compared with insulin glargine titrated to target in patients with type 2 diabetes (DURATION-3): an open-label randomised trial. *Lancet* 2010 Jun 26;375:2234-2243 [[20609969](#)] [10.1016/S0140-6736\(10\)60406-0](#)

### EAGLE, 0:

### ZC22565, 0:

### BC20965, 0:

### Trial 8078, :

## 3 lixisenatide

Trial	Treatments	Patients	Trials design and methods
<b>lixisenatide vs placebo (add on basal insulin)</b>			
<b>GETGOAL-L</b> <i>unpublished</i> [NCT00715624] n=328/167 follow-up: 24 weeks	AVE0010 (10,15 and 20 g) in association with basal insulin, with or without metformin versus placebo on top basal insulin	Type 2 diabetes mellitus insufficiently controlled with basal insulin with or without metformin	double-blind USA
<b>GetGoal Duo1</b> <i>ongoing</i> [NCT00975286] n=NA follow-up: 24 weeks	Lixisenatide as an add-on treatment to insulin glargine and metformin versus placebo	patients with type 2 diabetes insufficiently controlled with insulin glargine and metformin	Parallel groups double-blind USA
<b>GETGOAL-L-ASIA</b> <i>ongoing</i> [NCT00866658] n=NA follow-up: 24 weeks	24 weeks of AVE0010 versus placebo on Top of Basal Insulin +/- Sulfonylurea	Patients With Type 2 Diabetes Insufficiently Controlled With Basal Insulin With or Without Sulfonylurea	double-blind Japan

## References

GETGOAL-L, 0:

GetGoal Duo1, 0:

[10.2337/dc12-2462](https://doi.org/10.2337/dc12-2462)

GETGOAL-L-ASIA, 0:

## 4 thiazolidinediones

Trial	Treatments	Patients	Trials design and methods
<b>rosiglitazone vs</b>			
SB-712753/009 n=162/160 follow-up: 24 wk	Rosiglitazone, metformin, and insulin versus Insulin	patients with type 2 diabetes with insulin	Parallel groups
<b>rosiglitazone vs placebo</b>			
49653/136 n=148/143 follow-up: 26 wk	Rosiglitazone versus Placebo	patients with type 2 diabetes and chronic renal failure on Su, insulin, or both	Parallel groups
<b>pioglitazone + insulin vs placebo (add on insulin)</b>			
OPI-502 n=110/112 follow-up: 20 wk	Pioglitazone + insulin versus Placebo + insulin	Insulin-dependent DM-2	Parallel groups
PNFP-014 n=379/187 follow-up: 16 wk	Pioglitazone insulin versus Placebo + insulin	patients with type 2 diabetes	Parallel groups
<b>rosiglitazone vs placebo (add on insulin)</b>			
49653/085 n=138/139 follow-up: 26 wk	Rosiglitazone and insulin versus Insulin	patients with type 2 diabetes	Parallel groups
49653/095 n=196/96 follow-up: 26 wk	Rosiglitazone and insulin versus Insulin	patients with type 2 diabetes poorly controlled on insulin	Parallel groups
BRL 49653/347 [NCT00054782] n=418/212 follow-up: 24 wk	Rosiglitazone and insulin versus Insulin	patients with type 2 diabetes poorly controlled on insulin	Parallel groups

## References

SB-712753/009 , :

49653/136 , :

OPI-502, :

PNFP-014, :

49653/085 , :  
49653/095 , :  
BRL 49653/347 , :

## 5 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.

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