Clinical trials of antidiabetic drugs for diabetes type 2 in patients with insufficient glycaemic control with bitherapy

TrialResults-center www.trialresultscenter.org

1 DPP-4 inhibitors

Trial	Treatments	Patients	Trials design and methods
sitagliptin vs placebo (on-top glimepiride+/- metformine)			
Hermansen , 2007 n=NA follow-up:	sitagliptin 100 mg daily (add-on to ongoing stable doses of glimepiride, alone or in combination with metformin)ocumen versus placebo (add-on to ongoing stable doses of glimepiride, alone or in combination with metformin);	-	

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2 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

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3 DPP-4 inhibitors add on MET+TZD

Trial	Treatments	Patients	Trials design and methods
linagliptin vs placebo (add on MET+TZD)			
linagliptin 1218.61 *ongoing* [NCT00996658] n=NA follow-up:	Linagliptin (5 mg once daily) versus placebo (add on therapy to metformin in combination with pioglitazone)	Type 2 Diabetic Patients With Inadequate Glycaemic Control on Metformin in Combination With Pioglitazone	

References

linagliptin 1218.61, 0:

4 glucagon-like peptide analogs

Trial	Treatments	Patients	Trials design and methods
taspoglutide vs placebo			
BC20963 *ongoing* [NCT00744367] n=NA follow-up: 24 weeks	taspoglutide 10mg once weekly, taspoglutide 20 mg once weekly (after 4 weeks of taspoglutide 10 mg once weekly) versus placebo in addition to their continued stable metformin plus pioglitazone treatment	patients with type 2 diabetes mellitus inadequately controlled with metformin plus pioglitazone	double-blind USA
exenatide other doses vs placebo (add on MER+/-SU)			
Fineman , 2003 n=109 follow-up: 28 days	exenatide 3 regimen (0.08 micro g/kg) for 28 days versus placebo	patients with tyep 2 diabetes treated with diet and a sulfonylurea and/or metformin	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 desccent with type 2 diabetes and inadequate glycemic control taking metformin alone or Met and sulfonylureas	Parallel groups double-blind 4 countries
exenatide 10g/d vs placebo (add on SU+/-MET/TZD)			
Kadowaki (trial 8683) , 2009 n=111/40 follow-up: 12 weeks	Exenatide 10g daily for 12 weeks versus Placebo on-top of sulphonylureas +/-metformin/thiazolidinediones	Japanese patients with type 2 diabetes suboptimally controlled despite therapeutic dose of sulfonylurea, SU+biguanide or SU+thiazolidinedione	Parallel groups open Japan
exenatide 10g/d vs placebo (add on SU+MET)			

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Trial	Treatments	Patients	Trials design and methods
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
exenatide 20g/d vs placebo (add on TZD+/-MET)			
Zinman 20g/j , 2007 [NCT00099320] n=121/112 follow-up: 16 weeks	Exenatide 20 g daily versus Placebo on-top of thiazolidinediones+/-metformin	patients with type 2 diabetes that was suboptimally controlled with TZD treatment (with or without metformin)	double blind Canada, Spain, and the United States
Zinman 20g/j A MODIFIER , 2007 n=121/112 follow-up: 16 weeks	exenatide Subcutaneous abdominal injections of 10 microg twice daily versus placebo	patients with type 2 diabetes that was suboptimally controlled with TZD treatment (with or without metformin)	Parallel groups double-blind Canada, Spain, and the United States
liraglutide 1.2mg vs placebo (add on TZD+MET)			
LEAD-4 (1.2mg) , 2009 [NCT00333151] n=178/177 follow-up: 26 weeks	Liraglutide 1.2 daily versus Placebo on-top of thiazolidinediones + metformin	patients with type 2 diabetes, A1C 711% (previous OAD monotherapy >=3 months) or 710% (previous OAD combination therapy >=3 months), and BMI 45 kg/m2	Parallel groups double-blind USA, Canada
liraglutide 1.8mg vs placebo (add on TZD+MET)			
LEAD-4 (1.8mg) , 2009 [NCT00333151] n=178/177 follow-up: 26 weeks	Liraglutide 1.8 daily versus Placebo on-top of thiazolidinediones + metformin	patients with type 2 diabetes, A1C 711% (previous OAD monotherapy >=3 months) or 710% (previous OAD combination therapy >=3 months), and BMI 45 kg/m2	double-blind USA, Canada
exenatide once monthly vs weekly exenatide			
phase 2 exenatide once monthly *unpublished* n=121 follow-up: 20 weeks	exenatide once monthly at a low, medium or high dose, each administered once every four weeks, for a total of 20 weeks versus exenatide 2mg once weekly	adults with type 2 diabetes who were not achieving adequate glucose control using diet and exercise alone or with a stable regimen of metformin, pioglitazone, or both	Parallel groups open
taspoglutide vs exenatide			
BC21625 *ongoing* [NCT00717457] n=NA follow-up:	taspoglutide versus exenatide	patients with type 2 diabetes mellitus inadequately controlled with metformin, thiazolidinedione or a combination of both	parallel groups open USA
liraglutide 1.8mg vs exenatide on top MET/SU/MET+SU			

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Trial	Treatments	Patients	Trials design and methods
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 (add on SU/MET)			
Davis , 2007 [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
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 *ongoing* [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-nave 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 *ongoing* [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
taspoglutide vs pioglitazone			
BC21893 *ongoing* [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

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ZC22565, 0:

BC20965, 0:

BC21893, 0:

5 lixisenatide

Trial	Treatments	Patients	Trials design and methods
lixisenatide vs placebo (add on basal insulin)			
GetGoal Duo1 *ongoing* [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
lixisenatide vs placebo (add on MET+/-SU)			
GetGoal-M-As *ongoing* [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
lixisenatide vs placebo (add on SU+/-MET)			
GETGOAL-S *ongoing* [NCT00713830] n=NA follow-up: 24 weeks	AVE0010 in association with sulfonylurea without or with metformin versus placebo	patients with type 2 diabetes not adequately controlled with sulfonylurea	double-blind USA
lixisenatide vs placebo (add on TZD+/-MET)			
GETGOAL-P *ongoing* [NCT00763815] n=NA follow-up: 24 weeks	AVE0010 in association with pioglitazone with or without metformin versus placebo	Type 2 diabetes mellitus insufficiently controlled with pioglitazone with or without metformin	Parallel groups double-blind USA

References

GetGoal Duo1, 0:

10.2337/dc12-2462

GetGoal-M-As, 0:

GETGOAL-S, 0:

GETGOAL-P, 0:

6 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.