

Clinical trials of insulin secretagogues - DPP-4 inhibitors for diabetes type 2 in all types of patients

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1 DPP-4 inhibitors

Trial	Treatments	Patients	Trials design and methods
alogliptin vs			
Bosi , 2011 [NCT00432276] n=NA	-	-	
DeFronzo , 2008 [NCT00286455] n=NA	-	-	
Kaku , 2011 n=NA follow-up:	-	-	Japan
Pratley , 2009 [NCT00286468] n=NA follow-up:	-	-	
Pratley , 2009 [NCT00286494] n=NA follow-up:	-	-	
Rosenstock , 2009 [NCT00286429] n=NA follow-up:	-	-	
Rosenstock , 2010 [NCT00395512] n=NA follow-up:	-	-	
Seino , 2011 [NCT01263509] n=NA follow-up:	-	-	
Seino , 2011 n=NA follow-up:	-	-	Japan
linagliptin vs			

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Trial	Treatments	Patients	Trials design and methods
Forst , 2010 [NCT00309608] n=NA follow-up: 12 weeks	Linagliptin (1, 5, or 10 mg taken once daily) versus placebo (on top Metformin)	patients with type 2 diabetes mellitus who are not at goal with their HbA1c levels	double-blind France
saxagliptin vs			
Fonseca , 2012 [NCT00960076] n=NA follow-up:	-	-	
Forst , 2011 n=NA	-	-	
Gke , 2010 n=NA follow-up:	-	-	
Kawamori , 2012 [NCT00654381] n=NA follow-up:	-	-	
Nowicki , 2011 [NCT00614939] n=NA follow-up:	-	-	
Nowicki , 2011 [NCT00614939] n=NA follow-up:	-	-	
Scheen , 2010 n=NA	-	-	
Stenlf , 2010 n=NA	-	-	
Yang , 2011 [NCT00661362] n=NA follow-up:	-	-	
sitagliptin vs			
Stafford , 2011 [NCT00451113] n=NA follow-up:	-	older adults with type 2 diabetes mellitus	
vildagliptin vs			
NCT00101673 [NCT00101673] n=NA follow-up:	-	-	
vildagliptin monotherapy vs acarbose			

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Trial	Treatments	Patients	Trials design and methods
Pan , 2008 [NCT00110240] n=441/220 follow-up: 24 weeks	vildagliptin (100 mg daily, given as 50 mg twice daily) versus acarbose (up to 300 mg daily, given as three equally divided doses)	drug-naive patients with Type 2 diabetes	double-blind
vildagliptin monotherapy vs gliclazide			
Foley , 2009 [NCT00102388] n=NA follow-up: 2 years	monotherapy with vildagliptin 50 mg bid versus gliclazide up to 320 mg/day	drug-naive patients with type 2 diabetes	double-blind
vildagliptin vs gliclazide (add on MET)			
Filozof , 2009 [NCT00102466] n=513/494 follow-up: 52 weeks	vildagliptin (50 mg twice daily) versus gliclazide (up to 320 mg/day)	patients with Type 2 diabetes inadequately controlled with metformin	double-blind
linagliptin vs glimepiride			
CAROLINA , 2012 [NCT01243424] n=776/775 follow-up: 2 years	linagliptin versus glimepiride 1-4 mg QD	patients with type 2 diabetes at elevated cardiovascular risk receiving usual care	double-blind USA
vildagliptin vs glimepiride (add on MET)			
Matthews , 2010 n=NA follow-up: 2 years	vildagliptin versus glimepiride	patients with type 2 diabetes mellitus inadequately controlled (HbA1c 6.5-8.5%) by metformin monotherapy	Parallel groups double-blind
linagliptin low dose vs linagliptin			
linagliptin 1218.62 ongoing [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
vildagliptin + MET vs MET			
CLAF237A 23104 [NCT00396357] n=NA follow-up:	-	-	-
sitagliptin+pio vs metformin+pio			
Derosa , 2010 n=NA follow-up:	pioglitazone 30 mg plus sitagliptin 100 mg once a day versus pioglitazone 15 mg plus metformin 850 mg twice a day	poorly controlled type 2 diabetes mellitus patients	
alogliptin vs placebo			
EXAMINE , 2011 [NCT00968708] n=NA follow-up:	-	-	-

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Trial	Treatments	Patients	Trials design and methods
linagliptin vs placebo			
Del Prato [NCT00621140] n=NA follow-up: 24 weeks	Linagliptin monotherapy versus placebo	Type 2 Diabetic Patients With Insufficient Glycemic Control	double-blind Croatia
linagliptin 1218.46 <i>ongoing</i> [NCT00798161] n=NA follow-up: 24 weeks	-	drug naive or previously treated type 2 diabetic patients with insufficient glycaemic control	Canada
linagliptin1218.5 <i>ongoing</i> [NCT00328172] n=NA follow-up: 12 weeks	linagliptin (0.5, 2.5 and 5 mg daily) versus placebo	patients with Type 2 diabetes and insufficient glycemic control	
linagliptine 1218.50 <i>ongoing</i> [NCT00740051] n=NA follow-up: 18 weeks	Linagliptin versus Placebo	patients for whom metformin therapy is inappropriate (intolerability, contraindication)	double-blind USA
saxagliptin vs placebo			
SAVOR-TIMI 53 , 2013 [NCT01107886] n=16500 follow-up:	Saxagliptin 5 mg or 2.5 mg once daily versus Placebo	Patients With Type 2 Diabetes	Parallel groups USA
sitagliptin vs placebo			
Goldstein , 2007 [NCT00103857] n=NA follow-up:	sitagliptin 100 mg daily versus placebo	-	
Hanefeld , 2007 n=NA follow-up:	sitagliptin 25 mg or 50 mg or 100 mg daily versus placebo	-	
sitagliptin 50mg bid monotherapy vs placebo			
Scott* (sit vs pbo) , 2007 n=NA follow-up:	sitagliptin 50 mg b.i.d versus placebo	-	
vildagliptin vs placebo			
Mimori , 2006 n=NA follow-up:	vildagliptin 20 mg or 50 mg or 100 mg daily versus placebo	-	
NCT00351832 [NCT00351832] n=NA follow-up: 12 weeks	vildagliptin 50mg qd, 50mg bid or 100mg qd versus placebo	Patients With Type 2 Diabetes	Parallel groups Japan

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Trial	Treatments	Patients	Trials design and methods
Rosenstock , 2008 [NCT00237250] n=NA follow-up: 12 weeks	vildagliptin (50 mg q.d.) versus placebo	subjects with impaired glucose tolerance	double-blind
Scherbaum [2] , 2008 [NCT00101712] n=156/150 follow-up: 52 weeks	vildagliptin 50 mg qd versus placebo	drug-naive patients with type 2 diabetes and mild hyperglycaemia	Parallel groups double-blind
vildagliptin monotherapy vs placebo			
Ahren , 2009 [NCT00390520] n=NA follow-up:	vildagliptin (100 mg/d) versus placebo	drug-naive patients with type 2 diabetes	Cross over
Dejager [1] , 2007 [NCT00099905] n=NA follow-up: 24 weeks	vildagliptin 50 mg or 100 mg daily versus placebo	drug-naive patients with type 2 diabetes	double-blind
Foley , 2011 <i>unpublished</i> [NCT00260156] n=29/30 follow-up:	vildagliptin 100 mg versus placebo	drug-naive patients with type 2 diabetes and mild hyperglycaemia	
Kikuchi , 2009 n=NA follow-up:	vildagliptin 50mg bid versus placebo	Japanese patients with type 2 diabetes mellitus	Japan
Pi-Sunyer , 2007 [NCT00120536] n=NA follow-up: 24 weeks	vildagliptin 50 mg or 100 mg daily, imag versus placebo	drug-naive patients with type 2 diabetes	double-blind
Pratley , 2006 n=70/28 follow-up:	vildagliptin 25mg bid versus placebo	-	double-blind
Ristic , 2005 n=NA follow-up:	vildagliptin 25mg or 50mg or 100mg daily versus placebo	-	
vildagliptin vs placebo (add on current therapy)			
Lukashevich , 2011 [NA] n=NA follow-up: 24 weeks	vildagliptin (50 mg qd) versus placebo	patients with type 2 diabetes mellitus (T2DM) and moderate or severe renal impairment	
vildagliptin vs placebo (add on insulin)			
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

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Trial	Treatments	Patients	Trials design and methods
Fonseca , 2008 n=NA follow-up:	-	-	
vildagliptin vs placebo (add on MET)			
Ahren , 2004 n=56/51 follow-up: 12 weeks	vildagliptin 50 mg daily (add-on to metformin therapy)j versus placebo (add-on to metformin therapy)mag	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)m versus placebo (add-on to metformin therapy)mag	patients with type 2 diabetes inadequately controlled with metformin	double-blind
Bosi , 2009 [NCT00382096] n=1179 follow-up: 24 weeks	vildagliptin plus high-dose metformin combination therapy (50 mg + 1000 mg twice daily), versus high-dose metformin monotherapy (1000 mg twice daily).	treatment-naive patients with type 2 diabetes mellitus	
Goodman , 2009 n=125/122 follow-up: 24 weeks	ildagliptin 100 mg given in the morning, vildagliptin 100 mg given in the evening versus placebo	patients inadequately controlled with metformin	Parallel groups double-blind
NCT00396071 [NCT00396071] n=NA follow-up:	vildagliptin versus placebo	Patients With Type 2 Diabetes Treated With Metformin	Cross over
NCT00494884 (Wollmer) [NCT00494884] n=NA follow-up:	Vildagliptin 100 mg o.d. versus placebo	Patients With Type 2 Diabetes Inadequately Controlled With Metformin	
NCT00728351 [NCT00728351] n=NA follow-up:	Vildagliptin and Metformin (25/1000 mg Bid) versus Metformin Monotherapy (1000 mg Bid)	Patients With Type 2 Diabetes Inadequately Controlled With Metformin Monotherapy	
NCT00822211 [NCT00822211] n=NA follow-up: 24 weeks	Vildagliptin 50 mg Bid or qd versus placebo	Chinese Type 2 Diabetes Inadequately Controlled With Metformin Monotherapy	Parallel groups
linagliptin vs placebo (add on pioglitazone)			
Gomis , 2011 [NCT00641043] n=NA follow-up: 24 weeks	initial combination of 30 mg pioglitazone plus 5 mg linagliptin versus pioglitazone plus placebo	patients with inadequately controlled type 2 diabetes	
vildagliptin vs placebo (add on SU)			

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Trial	Treatments	Patients	Trials design and methods
Garber , 2008 [NCT00099944] n=515 follow-up: 24 weeks	vildagliptin (50 mg given once or twice daily) versus placebo	patients with type 2 diabetes inadequately controlled with a sulphonylurea	double-blind
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);	-	
vildagliptin vs voglibose			
Iwamoto , 2010 [NA] n=188/192 follow-up: 12 weeks	vildagliptin (50 mg bid, versus voglibose (0.2 mg tid	Japanese patients with T2D who were inadequately controlled with diet and exercise	double-blind Japan
NCT00368134 [NCT00368134] n=NA follow-up: 12 weeks	Vildagliptin 50 mg Bid versus Voglibose 0.2 mg Tid	patients with type 2 diabetes	Japan
saxagliptin vs glipizide			
saxagliptin n=NA follow-up: 52 weeks	saxagliptin versus titrated glipizide plus metformin	adult patients with type 2 diabetes and inadequate glycemic control	Parallel groups double-blind
sitagliptin 50mg bid monotherapy vs glipizide			
Scott* (sit vs glipi) , 2007 n=NA follow-up: 12 weeks	sitagliptin 50mg bid versus glipizide 5mg to 20 mg daily	patients with type 2 diabetes who have inadequate glycaemic control on diet and exercise	double-blind
sitagliptin vs metformin			
Goldstein (sit vs met) , 2007 n=NA follow-up:	sitagliptin 100 dailyly versus metformin 1000 mg or 2000 mg daily;	-	
Goldstein (sit+met vs met) , 2007 n=NA follow-up:	sitagliptin 50 mg daily plus metformin 1000 or 2000 mg daily <i>versus</i> <i>metformin1000or2000mgdaily</i>	-	
vildagliptin vs metformin			
Goke , 2008 n=NA follow-up:	vildagliptin (100 mg daily) versus metformin (2 000 mg daily).	drug-naive patients with type 2 diabetes	
Schweizer , 2007 [NCT00099866] n=526/254 follow-up: 52 weeks	vildagliptin 100mg versus metformin up to 2000 mg daily	drug-naive patients with Type 2 diabetes	

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Trial	Treatments	Patients	Trials design and methods
Schweizer , 2009 [NCT00246619] n=169/166 follow-up:	vildagliptin (100 mg daily versus metformin (titrated to 1500 mg daily	drug-naive patients with type 2 diabetes aged ≥65 years	
linagliptin + pioglitazone vs pioglitazone			
linagliptin 1264.3 ongoing [NCT01183013] n=NA follow-up: 30 weeks	linagliptin/pioglitazone (5/15, 5/30 and 5/45 mg) linagliptine versus pioglitazone	-	
sitagliptin vs pioglitazone			
Prez-Monte Verde , 2011 [NCT00541450] n=NA follow-up: 12 weeks	sitagliptin 100 mg qd versus pioglitazone 15 mg qd, up-titrated to 30 mg after 6 weeks	drug-naive patients with type 2 diabetes	double-blind
vildagliptin monotherapy vs pioglitazone			
Rosenstock** (vilda vs pio) , 2007 [NCT00101803] n=NA follow-up:	vildagliptin 100 mg daily daily versus pioglitazone 30 mg daily	drug-naive patients with type 2 diabetes	double-blind
vildagliptin vs rosiglitazone			
Rosenstock , 2009 [NCT00138619] n=396/202 follow-up:	vildagliptin (50 mg b.i.d versus rosiglitazone (8 mg q.d.,	drug-naive type 2 diabetes mellitus patients	double-blind
Rosenstock* (vilda vs rosi) , 2007 [NCT00099918] n=519/267 follow-up: 24 weeks	vildagliptin 100 mg daily daily versus rosiglitazone 8 mg once daily	drug-naive patients with type 2 diabetes	double-blind

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 Rosenstock* (vilda vs rosi), 2007:

2 DPP-4 inhibitors add on current treatment

Trial	Treatments	Patients	Trials design and methods
saxagliptin vs placebo (add on current treatment)			
saxagliptin, renal study n=NA follow-up: 12 weeks	saxagliptin versus placebo added to patients current diabetes treatment	patients with moderate to severe renal impairment or end-stage renal disease	Parallel groups

References

saxagliptin, renal study, :

3 DPP-4 inhibitors add on insulin

Trial	Treatments	Patients	Trials design and methods
saxagliptin vs placebo (add on insulin)			
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	

continued...

Trial	Treatments	Patients	Trials design and methods
vildagliptin vs placebo (add on insulin)			
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
Fonseca , 2008 n=NA follow-up:	-	-	
sitagliptin vs placebo (add on insulin+/-MET)			
Vilsbll , 2010 [NCT00395343] n=322/319 follow-up:	once-daily sitagliptin 100 mg versus placebo	patients with type 2 diabetes inadequately controlled on long-acting, intermediate-acting or premixed insulin	double-blind

References

CV181-057, :

Fonseca, 2007:

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Vilsbll, 2010:

4 DPP-4 inhibitors add on MET

Trial	Treatments	Patients	Trials design and methods
sitagliptin vs control (add on MET)			
Reasner , 2011 [NCT00482729] n=NA follow-up:	sitagliptin/metformin 50/500 mg bid uptitrated over 4 weeks to achieve maximum doses of sitagliptin/metformin 50/1000 mg bid versus metformin monotherapy	drug-naive patients with type 2 diabetes	Cross over NA
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
sitagliptin vs glimepiride (add on MET)			

continued...

Trial	Treatments	Patients	Trials design and methods
Arechavaleta , 2011 [NCT00701090] n=516/519 follow-up: 30 weeks	sitagliptin 100 mg daily versus glimepiride (starting dose 1 mg/day and up-titrated, based upon patient's self-monitoring of blood glucose results, to a maximum dose of up to 6 mg/day)	patients with type 2 diabetes inadequately controlled on metformin monotherapy	Parallel groups double-blind
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)			
Taskinen [NCT00601250] n=524/177 follow-up:	linagliptin 5 mg once daily versus placebo add on MET	patients with inadequately controlled type 2 diabetes for whom metformin therapy is inappropriate due to intolerability or contraindication	
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)			
CV181-066 [NCT00683657] n=NA follow-up:	Saxagliptin versus placebo	Subjects With Type 2 Diabetes Who Have Inadequate Glycemic Control With Diet And Exercise And A Stable Dose Of Metformin 1500 mg/Day	
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	
Jadzinsky , 2009 [NCT00327015] n=NA follow-up:	saxagliptin versus placebo	treatment-naive patients with type 2 diabetes (T2D) and inadequate glycaemic control	
sitagliptin vs placebo (add on MET)			
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);	-	

continued...

Trial	Treatments	Patients	Trials design and methods
raz , 2008 [NCT00337610] n=NA follow-up:	sitagliptin 100 mg once daily versus placebo	patients with type 2 diabetes	
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)mag	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)mag	patients with type 2 diabetes inadequately controlled with metformin	double-blind
Bosi , 2009 [NCT00382096] n=1179 follow-up: 24 weeks	vildagliptin plus high-dose metformin combination therapy (50 mg + 1000 mg twice daily), versus high-dose metformin monotherapy (1000 mg twice daily).	treatment-naive patients with type 2 diabetes mellitus	
Goodman , 2009 n=125/122 follow-up: 24 weeks	ildagliptin 100 mg given in the morning, vildagliptin 100 mg given in the evening versus placebo	patients inadequately controlled with metformin	Parallel groups double-blind
NCT00396071 [NCT00396071] n=NA follow-up:	vildagliptin versus placebo	Patients With Type 2 Diabetes Treated With Metformin	Cross over
NCT00494884 (Wollmer) [NCT00494884] n=NA follow-up:	Vildagliptin 100 mg o.d. versus placebo	Patients With Type 2 Diabetes Inadequately Controlled With Metformin	
NCT00728351 [NCT00728351] n=NA follow-up:	Vildagliptin and Metformin (25/1000 mg Bid) versus Metformin Monotherapy (1000 mg Bid)	Patients With Type 2 Diabetes Inadequately Controlled With Metformin Monotherapy	
NCT00822211 [NCT00822211] n=NA follow-up: 24 weeks	Vildagliptin 50 mg Bid or qd versus placebo	Chinese Type 2 Diabetes Inadequately Controlled With Metformin Monotherapy	Parallel groups
sitagliptin vs rosiglitazone (add on MET)			

continued...

Trial	Treatments	Patients	Trials design and methods
Rigby , 2010 n=NA follow-up: 16 weeks	sitagliptin phosphate, 100 mg daily versus rosiglitazone maleate, 4 mg daily	type 2 diabetes mellitus inadequately controlled by metformin monotherapy	open
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
sitagliptin vs Sulphonylurea (on top MET)			
Al Sifri , 2011 n=507/514 follow-up:	sitagliptin 100 mg qd versus prestudy sulphonylurea	Muslim patients with type 2 diabetes who were treated with a stable dose of a sulphonylurea with or without metformin for at least 3 months	Parallel groups open
vildagliptin vs TZD (add on MET)			
GALIAN (Blonde) , 2009 [NCT00396227] n=1653/825 follow-up:	vildagliptin 100 mg versus TZD (agent and dose at the investigators' discretion	patients inadequately controlled [haemoglobin A(1C) (HbA(1c)): 7-10%] on a stable dose of metformin (>or =1000 mg/day).	
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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Gallwitz, 2012:

Arechavaleta, 2011:

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DeFronzo, 2009:

Jadzinsky, 2009:

Charbonnel, 2006:

Nauck, 2007:

raz, 2008:
 Scott** (sit vs pbo on top met), 2007:
 Ahren, 2004:
 Bosi, 2007:
 Bosi, 2009:
 Goodman, 2009:
 NCT00396071, :
 NCT00494884 (Wollmer), :
 NCT00728351, :
 NCT00822211, :
 Rigby , 2010:
 saxagliptin vs sitagliptin, :
 Ferrannini, 2009:
 Al Sifri, 2011:
 GALIANT (Blonde), 2009:
 Bolli, 2008:

5 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:

6 DPP-4 inhibitors add on MET+TZD

Trial	Treatments	Patients	Trials design and methods
linagliptin vs placebo (add on MET+TZD)			
linagliptin 1218.61 <i>ongoing</i> [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:

7 DPP-4 inhibitors add on SU

Trial	Treatments	Patients	Trials design and methods
vildagliptin vs placebo (add on glimepiride)			
Kikuchi , 2010 [NCT00325117] n=102/100 follow-up: 12 weeks	vildagliptin 50mg twice-daily versus placebo	Japanese patients with Type 2 diabetes mellitus	double-blind Japan
linagliptin vs placebo (add on SU)			
Lewin , 2010 [NCT00819091] n=NA follow-up: 18 weeks	linagliptin 5 mg versus placebo (add-on to sulphonylurea)	patients with type 2 diabetes and insufficient glycaemic control	double-blind

References

Kikuchi, 2010:

Lewin, 2010:

8 DPP-4 inhibitors add on TZD

Trial	Treatments	Patients	Trials design and methods
sitagliptin vs placebo (add on PIO)			
Rosenstock , 2006 [NCT00086502] n=NA follow-up: 24 weeks	sitagliptin 100 mg once daily versus placebo	patients with type 2 diabetes and inadequate glycemic control	double-blind
saxagliptin vs placebo (add on TZD)			
Hollander [NCT00295633] n=NA follow-up:	saxagliptin (2.5 or 5 mg) versus placebo	patients with type 2 diabetes and inadequate control on thiazolidinedione alone	
sitagliptin vs placebo (on top PIO)			
Rosenstock (sit on top pio vs pbo) , 2006 [NCT00086502] n=NA follow-up:	sitagliptin 100 mg daily (add-on to pioglitazone therapy)sl versus placebo (add-on to pioglitazone therapy);	-	

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Trial	Treatments	Patients	Trials design and methods
vildagliptin vs placebo (on top pioglitazone)			
Garber , 2007 [NCT00099853] n=463 follow-up:	vildagliptin 50 or 100 mg daily (add-on to pioglitazone therapy) versus placebo (add-on to pioglitazone therapy)	-	
vildagliptin vs placebo (add on TZD)			
Rosenstock** (vilda + pio vs pio) , 2007 [NCT00101803] n=NA follow-up: 24 weeks	vildagliptin 50 mg or 100 mg daily plus 15 mg or 30 mg pioglitazone daily versus pioglitazone 30 mg daily	drug-naive patients with type 2 diabetes	double-blind

References

Rosenstock , 2006:

Hollander, :

Rosenstock (sit on top pio vs pbo), 2006:

Garber, 2007:

Rosenstock** (vilda + pio vs pio), 2007:

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9 DPP-4 inhibitors in combination

Trial	Treatments	Patients	Trials design and methods
saxagliptin + glyburide vs glyburide uptitration			
CV181-040 [NCT00313313] n=NA follow-up: 24 weeks	saxagliptin added to a submaximal sulphonylurea dose versus uptitration of sulphonylurea monotherapy	patients with type 2 diabetes and inadequate glycaemic control with sulphonylurea monotherapy	
saxagliptin plus metformin XR 1500mg vs metformin up to 2000mg			
CV181-085 [NCT00918138] n=NA follow-up:	Saxagliptin in Combination With Metformin XR 1500 mg versus Up-titrated Metformin XR to 2000 mg	Subjects With Type 2 Diabetes Who Have Inadequate Glycemic Control With Diet and Exercise and a Stable Dose of Metformin XR 1500 mg	

References

CV181-040, :

CV181-085, :

10 DPP-4 inhibitors monotherapy

Trial	Treatments	Patients	Trials design and methods
sitagliptin monotherapy vs metformin			
Aschner , 2010 [NCT00449930] n=528/522 follow-up: 24 weeks	once-daily sitagliptin 100 mg versus twice-daily metformin 1000 mg	treatment-naive patients with type 2 diabetes	double-blind
vildagliptin vs metformin			
Goke , 2008 n=NA follow-up:	vildagliptin (100 mg daily) versus metformin (2 000 mg daily).	drug-naive patients with type 2 diabetes	
Schweizer , 2007 [NCT00099866] n=526/254 follow-up: 52 weeks	vildagliptin 100mg versus metformin up to 2000 mg daily	drug-naive patients with Type 2 diabetes	
Schweizer , 2009 [NCT00246619] n=169/166 follow-up:	vildagliptin (100 mg daily) versus metformin (titrated to 1500 mg daily)	drug-naive patients with type 2 diabetes aged ≥ 65 years	
linagliptin vs placebo			
Del Prato [NCT00621140] n=NA follow-up: 24 weeks	Linagliptin monotherapy versus placebo	Type 2 Diabetic Patients With Insufficient Glycemic Control	double-blind Croatia
linagliptin 1218.46 <i>ongoing</i> [NCT00798161] n=NA follow-up: 24 weeks	-	drug naive or previously treated type 2 diabetic patients with insufficient glycaemic control	Canada
linagliptin1218.5 <i>ongoing</i> [NCT00328172] n=NA follow-up: 12 weeks	linagliptin (0.5, 2.5 and 5 mg daily) versus placebo	patients with Type 2 diabetes and insufficient glycemic control	
linagliptine 1218.50 <i>ongoing</i> [NCT00740051] n=NA follow-up: 18 weeks	Linagliptin versus Placebo	patients for whom metformin therapy is inappropriate (intolerability, contraindication)	double-blind USA
sitagliptin monotherapy vs placebo			
Aschner , 2006 [NCT00087516] n=NA follow-up: 24 weeks	sitagliptin 100 or 200 mg daily versus placebo	patients with type 2 diabetes	
Barzilai , 2011 [NCT00305604] n=NA follow-up: 24 weeks	once-daily sitagliptin (100 or 50 mg, depending on renal function) versus placebo	elderly patients with type 2 diabetes	double-blind US

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Trial	Treatments	Patients	Trials design and methods
Chan , 2008 n=65/26 follow-up: 12 weeks	sitagliptin versus placebo	patients with type 2 diabetes and chronic renal insufficiency	double-blind
Mohan , 2009 n=NA follow-up: 18 weeks	sitagliptin 100mg once daily monotherapy versus placebo	Chinese, Indian, and Korean patients with type 2 diabetes inadequately controlled by diet and exercise.	double-blind
Nonaka , 2008 [NCT00371007] n=NA follow-up:	sitagliptin 100 mg daily monotherapy versus placebo	Japanese patients with type 2 diabetes	double-blind
Raz , 2006 n=NA follow-up:	sitagliptin 100 mg (or 200 mg) daily versus placebo	patients with type 2 diabetes mellitus and inadequate glycaemic control	
vildagliptin monotherapy vs placebo			
Ahren , 2009 [NCT00390520] n=NA follow-up:	vildagliptin (100 mg/d) versus placebo	drug-naive patients with type 2 diabetes	Cross over
Dejager [1] , 2007 [NCT00099905] n=NA follow-up: 24 weeks	vildagliptin 50 mg or 100 mg daily versus placebo	drug-naive patients with type 2 diabetes	double-blind
Foley , 2011 <i>unpublished</i> [NCT00260156] n=29/30 follow-up:	vildagliptin 100 mg versus placebo	drug-naive patients with type 2 diabetes and mild hyperglycaemia	
Kikuchi , 2009 n=NA follow-up:	vildagliptin 50mg bid versus placebo	Japanese patients with type 2 diabetes mellitus	Japan
Pi-Sunyer , 2007 [NCT00120536] n=NA follow-up: 24 weeks	vildagliptin 50 mg or 100 mg daily, imag versus placebo	drug-naive patients with type 2 diabetes	double-blind
Pratley , 2006 n=70/28 follow-up:	vildagliptin 25mg bid versus placebo	-	double-blind
Ristic , 2005 n=NA follow-up:	vildagliptin 25mg or 50mg or 100mg daily versus placebo	-	
saxagliptin vs placebo (monotherapy)			
CV181-011 <i>unpublished</i> [NCT00121641] n=NA follow-up: 24 weeks	oral saxagliptin 2.5, 5, or 10 mg once daily versus placebo	-	

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Trial	Treatments	Patients	Trials design and methods
CV181-038 [NCT00316082] n=NA follow-up:	Saxagliptin monotherapy versus placebo	type 2 diabetic subjects who are not controlled with diet and exercise	
CV181-041 [NCT00374907] n=NA follow-up:	Saxagliptin versus placebo	Subjects With Type 2 Diabetes Who Are Not Controlled With Diet and Exercise	
Rosenstock , 2008 [NCT00950599] n=NA follow-up: 12 weeks	saxagliptin 2.5, 5, 10, 20 or 40 mg once daily versus placebo	drug-naive patients with T2DM and inadequate glycaemic control	
vildagliptin vs rosiglitazone			
Rosenstock , 2009 [NCT00138619] n=396/202 follow-up:	vildagliptin (50 mg b.i.d versus rosiglitazone (8 mg q.d.,	drug-naive type 2 diabetes mellitus patients	double-blind
Rosenstock* (vilda vs rosi) , 2007 [NCT00099918] n=519/267 follow-up: 24 weeks	vildagliptin 100 mg daily daily versus rosiglitazone 8 mg once daily	drug-naive patients with type 2 diabetes	double-blind
sitagliptin monotherapy vs voglibose			
Iwamoto , 2010 n=NA follow-up: 12 weeks	sitagliptin 50 mg once daily monotherapy versus voglibose 0.2 mg thrice daily before meals	Japanese patients with type 2 diabetes	double-blind

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Schweizer, 2007:

Schweizer, 2009:

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Aschner, 2006:

Barzilai, 2011:

Chan, 2008:

Mohan , 2009:

Nonaka, 2008:

Raz, 2006:

Ahren, 2009:

Dejager [1], 2007:
Foley, 2011:
Kikuchi, 2009:
Pi-Sunyer, 2007:
Pratley, 2006:
Ristic, 2005:
CV181-011, :
CV181-038, :
CV181-041, :
Rosenstock, 2008:
Rosenstock, 2009:
Rosenstock* (vilda vs rosi), 2007:
Iwamoto , 2010:

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