

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

TrialResults-center [www.trialresultscenter.org](http://www.trialresultscenter.org)

## 1 DPP-4 inhibitors

Trial	Treatments	Patients	Trials design and methods
<b>alogliptin vs</b>			
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
<b>linagliptin vs</b>			

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
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
<b>saxagliptin vs</b>			
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:	-	-	
<b>sitagliptin vs</b>			
Stafford , 2011 [NCT00451113] n=NA follow-up:	-	older adults with type 2 diabetes mellitus	
<b>vildagliptin vs</b>			
NCT00101673 [NCT00101673] n=NA follow-up:	-	-	
<b>vildagliptin monotherapy vs acarbose</b>			

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>Pan , 2008</b> [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
<b>vildagliptin monotherapy vs gliclazide</b>			
<b>Foley , 2009</b> [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
<b>vildagliptin vs gliclazide (add on MET)</b>			
<b>Filozof , 2009</b> [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
<b>linagliptin vs glimepiride</b>			
<b>CAROLINA , 2012</b> [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
<b>vildagliptin vs glimepiride (add on MET)</b>			
<b>Matthews , 2010</b> 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
<b>linagliptin low dose vs linagliptin</b>			
<b>linagliptin 1218.62 ongoing</b> [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
<b>vildagliptin + MET vs MET</b>			
<b>CLAF237A 23104</b> [NCT00396357] n=NA follow-up:	-	-	-
<b>sitagliptin+pio vs metformin+pio</b>			
<b>Derosa , 2010</b> 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	
<b>alogliptin vs placebo</b>			
<b>EXAMINE , 2011</b> [NCT00968708] n=NA follow-up:	-	-	-

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>linagliptin vs placebo</b>			
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
<b>saxagliptin vs placebo</b>			
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
<b>sitagliptin vs placebo</b>			
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	-	
<b>sitagliptin 50mg bid monotherapy vs placebo</b>			
Scott* (sit vs pbo) , 2007 n=NA follow-up:	sitagliptin 50 mg b.i.d versus placebo	-	
<b>vildagliptin vs placebo</b>			
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

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
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
<b>vildagliptin monotherapy vs placebo</b>			
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	-	
<b>vildagliptin vs placebo (add on current therapy)</b>			
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	
<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

continued...

Trial	Treatments	Patients	Trials design and methods
Fonseca , 2008 n=NA follow-up:	-	-	
<b>vildagliptin vs placebo (add on MET)</b>			
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
<b>linagliptin vs placebo (add on pioglitazone)</b>			
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	
<b>vildagliptin vs placebo (add on SU)</b>			

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>Garber , 2008</b> [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
<b>sitagliptin vs placebo (on-top glimepiride+/- metformine)</b>			
<b>Hermansen , 2007</b> 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);	-	
<b>vildagliptin vs voglibose</b>			
<b>Iwamoto , 2010</b> [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
<b>NCT00368134</b> [NCT00368134] n=NA follow-up: 12 weeks	Vildagliptin 50 mg Bid versus Voglibose 0.2 mg Tid	patients with type 2 diabetes	Japan
<b>saxagliptin vs glipizide</b>			
<b>saxagliptin</b> 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
<b>sitagliptin 50mg bid monotherapy vs glipizide</b>			
<b>Scott* (sit vs glipi) , 2007</b> 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
<b>sitagliptin vs metformin</b>			
<b>Goldstein (sit vs met) , 2007</b> n=NA follow-up:	sitagliptin 100 dailyly versus metformin 1000 mg or 2000 mg daily;	-	
<b>Goldstein (sit+met vs met) , 2007</b> n=NA follow-up:	sitagliptin 50 mg daily plus metformin 1000 or 2000 mg daily <i>versus</i> <i>metformin1000or2000mgdaily</i>	-	
<b>vildagliptin vs metformin</b>			
<b>Goke , 2008</b> n=NA follow-up:	vildagliptin (100 mg daily) versus metformin (2 000 mg daily).	drug-naive patients with type 2 diabetes	
<b>Schweizer , 2007</b> [NCT00099866] n=526/254 follow-up: 52 weeks	vildagliptin 100mg versus metformin up to 2000 mg daily	drug-naive patients with Type 2 diabetes	

continued...

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	
<b>linagliptin + pioglitazone vs pioglitazone</b>			
linagliptin 1264.3 ongoing [NCT01183013] n=NA follow-up: 30 weeks	linagliptin/pioglitazone (5/15, 5/30 and 5/45 mg) linagliptine versus pioglitazone	-	
<b>sitagliptin vs pioglitazone</b>			
Prez-Monteverde , 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
<b>vildagliptin monotherapy vs pioglitazone</b>			
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
<b>vildagliptin vs rosiglitazone</b>			
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

## References

### Bosi , 2011:

Bosi E, Ellis GC, Wilson CA, Fleck PR Alogliptin as a third oral antidiabetic drug in patients with type 2 diabetes and inadequate glycaemic control on metformin and pioglitazone: a 52-week, randomized, double-blind, active-controlled, parallel-group study. *Diabetes Obes Metab* 2011;13:1088-96 [21733058] [10.1111/j.1463-1326.2011.01463.x](https://doi.org/10.1111/j.1463-1326.2011.01463.x)

### DeFronzo , 2008:

DeFronzo RA, Fleck PR, Wilson CA, Mekki Q Efficacy and safety of the dipeptidyl peptidase-4 inhibitor alogliptin in patients with type 2 diabetes and inadequate glycaemic control: a randomized, double-blind, placebo-controlled study. *Diabetes Care* 2008;31:2315-7 [18809631] [10.2337/dc08-1035](https://doi.org/10.2337/dc08-1035)

### Kaku, 2011:

Kaku K, Itayasu T, Hiroi S, Hirayama M, Seino Y Efficacy and safety of alogliptin added to pioglitazone in Japanese patients with type 2 diabetes: a randomized, double-blind, placebo-controlled trial with an open-label long-term extension study. *Diabetes Obes Metab* 2011;13:1028-35 [21682833] [10.1111/j.1463-1326.2011.01460.x](https://doi.org/10.1111/j.1463-1326.2011.01460.x)

### Pratley, 2009:

Pratley RE, Kipnes MS, Fleck PR, Wilson C, Mekki Q Efficacy and safety of the dipeptidyl peptidase-4 inhibitor alogliptin in patients with type 2 diabetes inadequately controlled by glyburide monotherapy. *Diabetes Obes Metab* 2009;11:167-76 [19125778] [10.1111/j.1463-1326.2008.01016.x](https://doi.org/10.1111/j.1463-1326.2008.01016.x)



**Pratley, 2009:**

Pratley RE, Reusch JE, Fleck PR, Wilson CA, Mekki Q Efficacy and safety of the dipeptidyl peptidase-4 inhibitor alogliptin added to pioglitazone in patients with type 2 diabetes: a randomized, double-blind, placebo-controlled study. *Curr Med Res Opin* 2009;25:2361-71 [19650752] 10.1185/03007990903156111

**Rosenstock, 2009:**

Rosenstock J, Rendell MS, Gross JL, Fleck PR, Wilson CA, Mekki Q Alogliptin added to insulin therapy in patients with type 2 diabetes reduces HbA(1C) without causing weight gain or increased hypoglycaemia. *Diabetes Obes Metab* 2009;11:1145-52 [19758359] 10.1111/j.1463-1326.2009.01124.x

**Rosenstock, 2010:**

Rosenstock J, Inzucchi SE, Seufert J, Fleck PR, Wilson CA, Mekki Q Initial combination therapy with alogliptin and pioglitazone in drug-naïve patients with type 2 diabetes. *Diabetes Care* 2010;33:2406-8 [20724648] 10.2337/dc10-0159

**Seino, 2011:**

Seino Y, Fujita T, Hiroi S, Hirayama M, Kaku K Alogliptin plus voglibose in Japanese patients with type 2 diabetes: a randomized, double-blind, placebo-controlled trial with an open-label, long-term extension. *Curr Med Res Opin* 2011;27 Suppl 3:21-9 [22106975] 10.1185/03007995.2011.614936

**Seino, 2011:**

Seino Y, Fujita T, Hiroi S, Hirayama M, Kaku K Efficacy and safety of alogliptin in Japanese patients with type 2 diabetes mellitus: a randomized, double-blind, dose-ranging comparison with placebo, followed by a long-term extension study. *Curr Med Res Opin* 2011;27:1781-92 [21806314] 10.1185/03007995.2011.599371

**Forst, 2010:**

Forst T, Uhlig-Laske B, Ring A, Graefe-Mody U, Friedrich C, Herbach K, Woerle HJ, Dugi KA Linagliptin (BI 1356), a potent and selective DPP-4 inhibitor, is safe and efficacious in combination with metformin in patients with inadequately controlled Type 2 diabetes. *Diabet Med* 2010;27:1409-19 [21059094] 10.1111/j.1464-5491.2010.03131.x

**Fonseca, 2012:**

Fonseca V, Zhu T, Karyekar C, Hirshberg B Adding saxagliptin to extended-release metformin vs. uptitrating metformin dosage. *Diabetes Obes Metab* 2012;14:365-71 [22192246] 10.1111/j.1463-1326.2011.01553.x

**Forst, 2011:****Gke, 2010:**

Gke B, Gallwitz B, Eriksson J, Hellqvist A, Gause-Nilsson I Saxagliptin is non-inferior to glipizide in patients with type 2 diabetes mellitus inadequately controlled on metformin alone: a 52-week randomised controlled trial. *Int J Clin Pract* 2010;64:1619-31 [20846286] 10.1111/j.1742-1241.2010.02510.x

**Kawamori, 2012:**

Kawamori R, Inagaki N, Araki E, Watada H, Hayashi N, Horie Y, Sarashina A, Gong Y, von Eynatten M, Woerle HJ, Dugi KA Linagliptin monotherapy provides superior glycaemic control versus placebo or voglibose with comparable safety in Japanese patients with type 2 diabetes: a randomized, placebo and active comparator-controlled, double-blind study. *Diabetes Obes Metab* 2012;14:348-57 [22145698] 10.1111/j.1463-1326.2011.01545.x

Horie Y, Hayashi N, Dugi K, Takeuchi M Design, statistical analysis and sample size calculation of a phase IIb/III study of linagliptin versus voglibose and placebo. *Trials* 2009;10:82 [19732457] 10.1186/1745-6215-10-82

**Nowicki, 2011:**

Nowicki M, Rychlik I, Haller H, Warren M, Suchower L, Gause-Nilsson I, Shtzer KM Long-term treatment with the dipeptidyl peptidase-4 inhibitor saxagliptin in patients with type 2 diabetes mellitus and renal impairment: a randomised controlled 52-week efficacy and safety study. *Int J Clin Pract* 2011;65:1230-9 [21977965] 10.1111/j.1742-1241.2011.02812.x

**Nowicki, 2011:**

Nowicki M, Rychlik I, Haller H, Warren ML, Suchower L, Gause-Nilsson I Saxagliptin improves glycaemic control and is well tolerated in patients with type 2 diabetes mellitus and renal impairment. *Diabetes Obes Metab* 2011;13:523-32 [21332627] 10.1111/j.1463-1326.2011.01382.x

**Scheen , 2010:**

Scheen AJ, Charpentier G, Ostgren CJ, Hellqvist A, Gause-Nilsson I Efficacy and safety of saxagliptin in combination with metformin compared with sitagliptin in combination with metformin in adult patients with type 2 diabetes mellitus. *Diabetes Metab Res Rev* 2010;26:540-9 [20824678] 10.1002/dmrr.1114

**Stenlf , 2010:**

Stenlf K, Raz I, Neutel J, Ravichandran S, Berglind N, Chen R Saxagliptin and metformin XR combination therapy provides glycemic control over 24 hours in patients with T2DM inadequately controlled with metformin. *Curr Med Res Opin* 2010;26:2355-63 [20804445] 10.1185/03007995.2010.511090

**Yang, 2011:**

Yang W, Pan CY, Tou C, Zhao J, Gause-Nilsson I Efficacy and safety of saxagliptin added to metformin in Asian people with type 2 diabetes mellitus: a randomized controlled trial. *Diabetes Res Clin Pract* 2011;94:217-24 [21871686] 10.1016/j.diabres.2011.07.035

**Stafford , 2011:**

Stafford S, Elahi D, Meneilly GS Effect of the dipeptidyl peptidase-4 inhibitor sitagliptin in older adults with type 2 diabetes mellitus. *J Am Geriatr Soc* 2011;59:1148-9 [21668924] 10.1111/j.1532-5415.2011.03438.x

**NCT00101673, :**

Pratley RE, Schweizer A, Rosenstock J, Foley JE, Banerji MA, Pi-Sunyer FX, Mills D, Dejager S Robust improvements in fasting and prandial measures of beta-cell function with vildagliptin in drug-naive patients: analysis of pooled vildagliptin monotherapy database. *Diabetes Obes Metab* 2008;10:931-8 [18093207] 10.1111/j.1463-1326.2007.00835.x

**Pan, 2008:**

Pan C, Yang W, Barona JP, Wang Y, Niggli M, Mohideen P, Wang Y, Foley JE Comparison of vildagliptin and acarbose monotherapy in patients with Type 2 diabetes: a 24-week, double-blind, randomized trial. *Diabet Med* 2008;25:435-41 [18341596] 10.1111/j.1464-5491.2008.02391.x

**Foley, 2009:**

Foley JE, Sreenan S Efficacy and safety comparison between the DPP-4 inhibitor vildagliptin and the sulfonylurea gliclazide after two years of monotherapy in drug-naive patients with type 2 diabetes. *Horm Metab Res* 2009;41:905-9 [19705345] 10.1055/s-0029-1234042

**Filozof, 2009:**

Filozof C, Gautier JF A comparison of efficacy and safety of vildagliptin and gliclazide in combination with metformin in patients with Type 2 diabetes inadequately controlled with metformin alone: a 52-week, randomized study. *Diabet Med* 2010 Mar;27:318-26 [20536495] 10.1111/j.1464-5491.2010.02938.x

**CAROLINA, 2012:**

Gallwitz B, Rosenstock J, Rauch T, Bhattacharya S, Patel S, von Eynatten M, Dugi KA, Woerle HJ 2-year efficacy and safety of linagliptin compared with glimepiride in patients with type 2 diabetes inadequately controlled on metformin: a randomised, double-blind, non-inferiority trial. *Lancet* 2012 Aug 4;380:475-83 [22748821] 10.1016/S0140-6736(12)60691-6

**Matthews , 2010:**

Matthews DR, Dejager S, Ahren B, Fonseca V, Ferrannini E, Couturier A, Foley JE, Zinman B Vildagliptin add-on to metformin produces similar efficacy and reduced hypoglycaemic risk compared with glimepiride, with no weight gain: results from a 2-year study. *Diabetes Obes Metab* 2010;12:780-9 [20649630] 10.1111/j.1463-1326.2010.01233.x

**linagliptin 1218.62, 0:**

**CLAF237A 23104, :**

**Derosa , 2010:**

Derosa G, Maffioli P, Salvadeo SA, Ferrari I, Ragonesi PD, Querci F, Franzetti IG, Gadaleta G, Ciccirelli L, Piccinni MN, D'Angelo A, Cicero AF Effects of sitagliptin or metformin added to pioglitazone monotherapy in poorly controlled type 2 diabetes mellitus patients. *Metabolism* 2010;59:887-95 [20015525] 10.1016/j.metabol.2009.10.007

**EXAMINE, 2011:**

White WB, Bakris GL, Bergenstal RM, Cannon CP, Cushman WC, Fleck P, Heller S, Mehta C, Nissen SE, Perez A, Wilson C, Zannad F EXamination of cardiovascular outcomes with alogliptin versus standard of care in patients with type 2 diabetes mellitus and acute coronary syndrome (EXAMINE): a cardiovascular safety study of the dipeptidyl peptidase 4 inhibitor alogliptin in patients with type 2 diabetes with acute coronary syndrome. *Am Heart J* 2011;162:620-626.e1 [21982652] 10.1016/j.ahj.2011.08.004

White WB, Cannon CP, Heller SR, Nissen SE, Bergenstal RM, Bakris GL, Perez AT, Fleck PR, Mehta CR, Kupfer S, Wilson C, Cushman WC, Zannad F Alogliptin after Acute Coronary Syndrome in Patients with Type 2 Diabetes. *N Engl J Med* 2013 Sep 2;: [23992602] 10.1056/NEJMoa1305889

**Del Prato, 0:**

Del Prato S, Barnett A, Huisman H, et al. Linagliptin monotherapy improves glycaemic control and measures of beta-cell function in Type 2 diabetes. Poster no 695-P, 70th American Diabetes Association Scientific Sessions, June 2010, Orlando, Florida, U.S.A

Del Prato S, Barnett AH, Huisman H, Neubacher D, Woerle HJ, Dugi KA Effect of linagliptin monotherapy on glycaemic control and markers of  $\beta$ -cell function in patients with inadequately controlled type 2 diabetes: a randomized controlled trial. *Diabetes Obes Metab* 2011;13:258-67 [[21205122](#)] [10.1111/j.1463-1326.2010.01350.x](#)

**linagliptin 1218.46, 0:**

**linagliptin1218.5, 0:**

**linagliptine 1218.50, 0:**

**SAVOR-TIMI 53, 2013:**

Scirica BM, Bhatt DL, Braunwald E, Steg PG, Davidson J, Hirshberg B, Ohman P, Price DL, Chen R, Udell J, Raz I The design and rationale of the saxagliptin assessment of vascular outcomes recorded in patients with diabetes mellitus-thrombolysis in myocardial infarction (SAVOR-TIMI) 53 study. *Am Heart J* 2011;162:818-825.e6 [[22093196](#)] [10.1016/j.ahj.2011.08.006](#)

Scirica BM, Bhatt DL, Braunwald E, Steg PG, Davidson J, Hirshberg B, Ohman P, Frederich R, Wiviott SD, Hoffman EB, Cavender MA, Udell JA, Desai NR, Mozenon O, McGuire DK, Ray KK, Leiter LA, Raz I Saxagliptin and Cardiovascular Outcomes in Patients with Type 2 Diabetes Mellitus. *N Engl J Med* 2013 Sep 2;: [[23992601](#)] [10.1056/NEJMoa1307684](#)  
**Goldstein, 2007:**

Goldstein BJ, Feinglos MN, Lunceford JK, Johnson J, Williams-Herman DE Effect of initial combination therapy with sitagliptin, a dipeptidyl peptidase-4 inhibitor, and metformin on glycemic control in patients with type 2 diabetes. *Diabetes Care* 2007;30:1979-87 [[17485570](#)] [10.2337/dc07-0627](#)

**Hanefeld, 2007:**

Hanefeld M, Herman GA, Wu M, Mickel C, Sanchez M, Stein PP Once-daily sitagliptin, a dipeptidyl peptidase-4 inhibitor, for the treatment of patients with type 2 diabetes. *Curr Med Res Opin* 2007;23:1329-39 [[17559733](#)] [10.1185/030079907X188152](#)

**Scott\* (sit vs pbo), 2007:**

Scott R, Wu M, Sanchez M, Stein P Efficacy and tolerability of the dipeptidyl peptidase-4 inhibitor sitagliptin as monotherapy over 12 weeks in patients with type 2 diabetes. *Int J Clin Pract* 2007;61:171-80 [[17156104](#)] [10.1111/j.1742-1241.2006.01246.x](#)

**Mimori, 2006:**

**NCT00351832, :**

**Rosenstock, 2008:**

**Scherbaum [2], 2008:**

**Ahren, 2009:**

**Dejager [1], 2007:**

**Foley, 2011:**

**Kikuchi, 2009:**

**Pi-Sunyer, 2007:**

**Pratley, 2006:**

**Ristic, 2005:**

**Lukashevich , 2011:**

**Fonseca, 2007:**

**Fonseca , 2008:**

**Ahren, 2004:**

**Bosi, 2007:**

**Bosi, 2009:**

**Goodman, 2009:**

**NCT00396071, :**

**NCT00494884 (Wollmer), :**

**NCT00728351, :**

NCT00822211, :  
 Gomis, 2011:  
 Garber, 2008:  
 Hermansen, 2007:  
 Iwamoto, 2010:  
 NCT00368134, :  
 saxagliptin, :  
 Scott\* (sit vs glipi), 2007:  
 Goldstein (sit vs met), 2007:  
 Goldstein (sit+met vs met), 2007:  
 Goke, 2008:  
 Schweizer, 2007:  
 Schweizer, 2009:  
 linagliptin 1264.3, 0:  
 Prez-Monteverde, 2011:  
 Rosenstock\*\* (vilda vs pio), 2007:  
 Rosenstock, 2009:  
 Rosenstock\* (vilda vs rosi), 2007:

## 2 DPP-4 inhibitors add on current treatment

Trial	Treatments	Patients	Trials design and methods
<b>saxagliptin vs placebo (add on current treatment)</b>			
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
<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	

continued...

Trial	Treatments	Patients	Trials design and methods
<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
Fonseca , 2008 n=NA follow-up:	-	-	
<b>sitagliptin vs placebo (add on insulin+/-MET)</b>			
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:

Fonseca , 2008:

Vilsbll, 2010:

## 4 DPP-4 inhibitors add on MET

Trial	Treatments	Patients	Trials design and methods
<b>sitagliptin vs control (add on MET)</b>			
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
<b>linagliptin vs glimepiride (add on MET)</b>			
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
<b>sitagliptin vs glimepiride (add on MET)</b>			

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>Arechavaleta , 2011</b> [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
<b>alogliptin vs placebo (add on MET)</b>			
<b>Nauck , 2009</b> [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
<b>linagliptin vs placebo (add on MET)</b>			
<b>Taskinen</b> [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	
<b>linagliptin 1218.65</b> <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
<b>saxagliptin vs placebo (add on MET)</b>			
<b>CV181-066</b> [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	
<b>CV181-080</b> [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	
<b>DeFronzo , 2009</b> [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	
<b>Jadzinsky , 2009</b> [NCT00327015] n=NA follow-up:	saxagliptin versus placebo	treatment-naive patients with type 2 diabetes (T2D) and inadequate glycaemic control	
<b>sitagliptin vs placebo (add on MET)</b>			
<b>Charbonnel , 2006</b> [NCT0086515] n=NA follow-up:	sitagliptin 100 mg daily (add-on to metformin therapy) versus placebo (add-on to metformin therapy);	-	
<b>Nauck , 2007</b> [NCT00094770] n=NA follow-up:	sitagliptin 100 mg daily (add-on to metformin therapy) versus placebo (add-on to metformin therapy);	-	

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
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	
<b>vildagliptin vs placebo (add on MET)</b>			
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
<b>sitagliptin vs rosiglitazone (add on MET)</b>			

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>Rigby , 2010</b> 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
<b>saxagliptin vs sitagliptin (add on MET)</b>			
<b>saxagliptin vs sitagliptin</b> 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
<b>vildagliptin vs Sulfonylurea (add on to MET)</b>			
<b>Ferrannini , 2009</b> [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
<b>sitagliptin vs Sulphonylurea (on top MET)</b>			
<b>Al Sifri , 2011</b> 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
<b>vildagliptin vs TZD (add on MET)</b>			
<b>GALIAN (Blonde) , 2009</b> [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).	
<b>vildagliptin vs pioglitazone (add on MET)</b>			
<b>Bolli , 2008</b> [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

## References

Reasner, 2011:

Gallwitz, 2012:

Arechavaleta, 2011:

Nauck, 2009:

Taskinen, 0:

linagliptin 1218.65, 0:

CV181-066, :

CV181-080, :

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
<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:

## 6 DPP-4 inhibitors add on MET+TZD

Trial	Treatments	Patients	Trials design and methods
<b>linagliptin vs placebo (add on MET+TZD)</b>			
<b>linagliptin 1218.61</b> <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
<b>vildagliptin vs placebo (add on glimepiride)</b>			
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
<b>linagliptin vs placebo (add on SU)</b>			
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
<b>sitagliptin vs placebo (add on PIO)</b>			
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
<b>saxagliptin vs placebo (add on TZD)</b>			
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	
<b>sitagliptin vs placebo (on top PIO)</b>			
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);	-	

continued...

Trial	Treatments	Patients	Trials design and methods
<b>vildagliptin vs placebo (on top pioglitazone)</b>			
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)	-	
<b>vildagliptin vs placebo (add on TZD)</b>			
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:

19

## 9 DPP-4 inhibitors in combination

Trial	Treatments	Patients	Trials design and methods
<b>saxagliptin + glyburide vs glyburide uptitration</b>			
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	
<b>saxagliptin plus metformin XR 1500mg vs metformin up to 2000mg</b>			
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
<b>sitagliptin monotherapy vs metformin</b>			
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
<b>vildagliptin vs metformin</b>			
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 $\geq 65$ years	
<b>linagliptin vs placebo</b>			
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
<b>sitagliptin monotherapy vs placebo</b>			
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

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
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	
<b>vildagliptin monotherapy vs placebo</b>			
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	-	
<b>saxagliptin vs placebo (monotherapy)</b>			
CV181-011 <i>unpublished</i> [NCT00121641] n=NA follow-up: 24 weeks	oral saxagliptin 2.5, 5, or 10 mg once daily versus placebo	-	

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
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	
<b>vildagliptin vs rosiglitazone</b>			
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
<b>sitagliptin monotherapy vs voglibose</b>			
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

## References

Aschner, 2010:

Goke, 2008:

Schweizer, 2007:

Schweizer, 2009:

Del Prato, 0:

linagliptin 1218.46, 0:

linagliptin1218.5, 0:

linagliptine 1218.50, 0:

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:**

## 11 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.