

Clinical trials of insulin secretagogues for diabetes type 2 in all type 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			
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

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Trial	Treatments	Patients	Trials design and methods
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-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
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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Ristic, 2005:

Lukashevich , 2011:

Fonseca, 2007:

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Ahren, 2004:

Bosi, 2007:

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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
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

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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);	-	

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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)	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)	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

References

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Gallwitz, 2012:

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Nauck, 2009:

Taskinen, 0:

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 Ahren, 2004:
 Bosi, 2007:
 Bosi, 2009:
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 NCT00396071, :
 NCT00494884 (Wollmer), :
 NCT00728351, :
 NCT00822211, :
 Rigby , 2010:
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 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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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 meglitinides (glinides)

Trial	Treatments	Patients	Trials design and methods
repaglinide vs ???			
YSRE0001 [NCT00336310] n=NA follow-up: 12 weeks	Repaglinide versus NA	-	double-blind Taiwan
repaglinide vs control (add on MET)			
Moses , 1999 n=27/27 follow-up: 12 weeks	prestudy dose of metformin with the addition of repaglinide versus prestudy dose of metformin	patients with type 2 diabetes who had inadequate glycemic control (HbA1c >7.1%) when receiving the antidiabetic agent metformin	Parallel groups open
repaglinide vs glibenclamide			
Landgraf , 1999 n=NA follow-up: 14 weeks	repaglinide, administered preprandially three times daily versus glibenclamide, given preprandially once or twice daily	-	double-blind
Marbury , 1999 n=NA	-	-	
Wolffenbittel , 1999 n=211/109 follow-up: 1 year	repaglinide (0.5-4 mg t.i.d.) versus glyburide (1.75-10.5 mg daily)	-	double-blind
nateglinide vs glibenclamide (add on MET)			
Derosa , 2009 n=124/124 follow-up: 12 months	nateglinide versus glibenclamide	nave type 2 diabetic patients treated with metformin	double-blind

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Trial	Treatments	Patients	Trials design and methods
repaglinide vs gliclazide			
AGEE-3783 [NCT01022762] n=NA follow-up:	repaglinide (1 mg repaglinide twice daily (weeks 0-4), titrated) versus gliclazide (80 mg gliclazide once daily (weeks 0-4), titrated)	Chinese subjects with type 2 diabetes who never have been treated with oral anti-diabetic drugs	China
repaglinide vs glipizide			
Madsbad , 2001 n=256 follow-up: 1 year	repaglinide, 1-4 mg at mealtimes versus glipizide, 5-15 mg daily	-	double-blind
nateglinide vs glyburide (add on MET)			
PRESERVE-beta n=NA follow-up:	-	-	
repaglinide + insulin vs insulin			
AGEE-1524 [NCT00799448] n=NA follow-up:	repaglinide combined with insulin NPH versus biphasic human insulin 30 alone	type 2 diabetics inadequately controlled with sulfonylurea (SU) +/- biguanide therapy	open Greece
AGEE-3020 n=NA	-	-	
mitiglinide+voglibose vs insulin glargine			
GLORIA [NCT00663884] n=NA follow-up: 16 weeks	combination therapy of 10 mg mitiglinide or 0.2mg voglibose versus insulin glargine	diabetic patients whose glycemic control were not enough despite administration of oral antidiabetic drug or insulin glargine	open Korea
nateglinide + metformin vs metformin			
Horton DOUBLON , 2000 n=172/178 follow-up: 24 weeks	nateglinide (120 mg, ac) and metformin (500 mg, tid) versus 500 mg metformin three times a day	-	
repaglinide vs metformin			
ReMet [NCT00118950] n=NA follow-up:	Repaglinide versus Metformin	Non-Obese Type 2 Diabetic Patients Uncontrolled by Diet	double-blind Denmark
Lund , 2007 n=NA follow-up:	repaglinide 2 mg thrice daily versus metformin 1 g twice daily	non-obese patients with type 2 diabetes	Cross over double-blind
repaglinide + metformin vs metformin			
AGEE-1411 [NCT01465152] n=NA follow-up:	-	-	open Spain

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Trial	Treatments	Patients	Trials design and methods
repaglinide vs Metformin (add on insulin)			
Reform [NCT00118963] n=NA follow-up:	Repaglinide + BIAsp30 versus Metformin + BIAsp30	non-obese patients with type-2-diabetes, uncontrolled on diet alone	double-blind
mitiglinide vs nateglinide			
Gao [NCT00461617] n=291 follow-up: 20 weeks	mitiglinide 10 - 20 mg three times daily versus nateglinide 120 mg three times daily	Chinese type 2 diabetes mellitus patients	Parallel groups double-blind
mitiglinide vs on top insulin glargine			
Kumashiro , 2007 n=NA follow-up:	mitiglinide versus on top of once daily insulin glargine	-	
repaglinide vs on top pioglitazone			
Raskin , 2001 n=NA	-	-	
repaglinide vs on top rosiglitazone			
Raskin , 2001 n=NA	-	-	
repaglinide vs on top troglitazone			
Raskin , 2000 n=256 follow-up: 22 weeks	repaglinide (0.54.0 mg at meals), versus combination of repaglinide (14 mg at meals) and troglitazone (200600 mg once daily)	Patients with type 2 diabetes who had inadequate glycemic control (HbA1c 7.0%) during previous monotherapy	open
nateglinide vs placebo			
CDJN608AUS13 n=NA	-	-	
CDJN608AUS13 n=NA	-	-	
CDJN608A ES03 <i>unpublished</i> n=NA follow-up:	-	-	
NAVIGATOR n=NA follow-up:	-	patients with impaired glucose toler-ance (IGT)	
Schwarz , 2008 n=66 follow-up: 12 weeks	nateglinide monotherapy (120 mg, before meals) versus placebo	drug-naive patients with T2DM aged ≥ 65 years	double-blind
Schwarz (study 2) , 2008 n=NA follow-up: 12 weeks	nateglinide monotherapy (120 mg, before meals) versus	drug-naive patients with T2DM aged ≥ 65 years	double-blind

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Trial	Treatments	Patients	Trials design and methods
Hanefeld , 1990 n=229/60 follow-up: 12 weeks	nateglinide at doses of 30 mg, 60 mg, 120 mg, or 180 mg versus placebo	-	Parallel groups double-blind
Horton , 2000 n=179/172 follow-up:	120 mg nateglinide before meals versus placebo	patients with an HbA1c level between 6.8 and 11.0% during a 4-week placebo run-in	Parallel groups double-blind
Mari , 2005 n=108 follow-up: 24 weeks	30, 60, or 120 mg nateglinide versus placebo	mild type 2 diabetic men and women (fasting glucose 7.0-8.3 mmol/l) on diet treatment	Parallel groups double-blind
Marre , 2002 n=NA follow-up:	nateglinide 60 mg, 120 mg before three meals versus placebo	metformin-treated patients with HbA1c between 6.8% and 11%	Parallel groups double-blind
Moses , 2001 n=408 follow-up: 16 weeks	0.5 mg repaglinide at mealtimes (increased to 1 mg after 4 weeks depending on blood glucose response) versus placebo	patients with type 2 diabetes considered poorly controlled by diet, but without a history of previous antidiabetic medication	Parallel groups double-blind
Saloranta , 2002 n=675 follow-up: 24 weeks	nateglinide (30, 60, or 120 mg, with meals). versus placebo	patients with type 2 diabetes but only moderately elevated fasting plasma glucose (FPG = 7.0-8.3 mmol/liter)	Parallel groups double-blind
repaglinide vs placebo			
Goldberg , 1998 n=66/33 follow-up: 18 weeks	repaglinide versus placebo	patients with type 2 diabetes	Parallel groups double-blind
Jovanovic , 2000 n=286/75 follow-up: 24 weeks	repaglinide 1 mg (n = 140), or repaglinide 4 mg (n = 146) versus placebo	-	double-blind
Chuang , 1999 n=NA	-	-	
Bech , 2003 n=253 follow-up: 16 weeks	repaglinide initiated at 0.5 mg per meal, increased to 1 mg after 4 weeks if fasting plasma glucose exceeded 7.8 mmol/l. versus placebo	pharmacotherapy-naive patients with Type 2 diabetes	Parallel groups double-blind
Goldberg , 1998 n=66/33 follow-up:	repaglinide versus placebo	type 2 diabetes	Parallel groups double-blind
Jovanovic , 2000 n=286/75 follow-up: 24 weeks	repaglinide 1 mg or repaglinide 4 mg versus placebo	-	Parallel groups double-blind
nateglinide vs placebo (add on insulin)			

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Trial	Treatments	Patients	Trials design and methods
Dashora , 2007 n=55 follow-up: 16 weeks	nateglinide before meals versus placebo	-	double-blind
nateglinide vs placebo (add on insulin+MET)			
Juurinen , 2009 n=NA follow-up: 24 weeks	nateglinide (120 mg three times daily) before main meals versus placebo (add on insulin+MET)	Type 2 diabetes treated with the combination of basal insulin and metformin	Parallel groups double-blind
mitiglinide vs placebo (add on MET)			
NCT01037842 [NCT01037842] n=NA follow-up: 16 weeks	mitiglinide versus placebo	patients with type 2 diabetes who show inadequate glycemic control with metformin monotherapy	double-blind Korea
EX-1510-CT-003 [NCT00519142] n=NA follow-up: 24 weeks	metformin + mitiglinide three times a day with meals versus (metformin + placebo for mitiglinide)	patients with Type 2 diabetes mellitus not well controlled with metformin alone	double-blind US
nateglinide vs placebo (add on standard treatment)			
NCT00402909 [NCT00402909] n=NA follow-up:	-	patients with type 2 diabetes who are not achieving glycemic control with glargine, metformin and/or thiazolidinedione only	double-blind
nateglinide vs placebo (add on TZD)			
026-CL-004 <i>ongoing</i> [NCT00189774] n=NA follow-up:	nateglinide versus placebo (on top pioglitazone)	inadequately controlled type 2 diabetic patients with pioglitazone treatment	double-blind Japan
repaglinide vs placebo (on top bedtime NPH-insulin)			
Landin-Olsson , 1999 n=NA	-	-	-
mitiglinide vs placebo (on top pioglitazone)			
Kaku , 2009 n=NA follow-up: 16 weeks	additional mitiglinide 5 or 10 mg tid versus placebo on top pioglitazone	Japanese type 2 diabetic patients who are insufficiently controlled by pioglitazone monotherapy	Parallel groups multicenter
metformin + repaglinide vs repaglinide			
AGEE-1411 [NCT01465152] n=NA follow-up: 24 weeks	metformin and repaglinide versus repaglinide	subjects with type 2 diabetes in which diet and exercise have failed	open Spain
nateglinide vs repaglinide			
Rosenstock , 2004 n=74/76 follow-up: 16 week	nateglinide monotherapy versus repaglinide monotherapy	type 2 diabetic patients previously treated with diet and exercise	open

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Trial	Treatments	Patients	Trials design and methods
Li , 2009 n=NA follow-up:	Nateglinide versus repaglinide	-	
Li , 2007 n=115/115 follow-up: 12 weeks	nateglinide 90 mg three times daily versus repaglinide 1.0 mg three times daily	Chinese patients with type 2 diabetes	Parallel groups
repaglinide + metformin vs repaglinide			
AGEE-3705 [NCT00819741] n=NA follow-up:	repaglinide plus metformin versus repaglinide alone	Chinese subjects with type 2 diabetes having an HbA1c (glycosylated haemoglobin A1c) over 8.5 % and who never have taken oral sugar-lowering drugs before	open China
AGEE-3018 n=NA follow-up:	-	-	
repaglinide + metformin vs rosiglitazone + metformin			
Raskin , 2009 [NCT00399711] n=NA follow-up: 26 weeks	repaglinide and metformin fixed dose combination tablet given as twice daily versus twice daily rosiglitazone and metformin fixed dose combination	subjects with type 2 diabetes currently on monotherapy	open USA
repaglinide + metformin vs SU or MET			
AGEE-3017 [NCT00568984] n=NA follow-up:	combination therapy of repaglinide and metformin versus conventional treatment with a sulphonylurea or metformin in monotherapy	-	China
nateglinide vs gliclazide (add on MET)			
Ristic , 2006 n=133/129 follow-up: 24 weeks	nateglinide plus metformin versus gliclazide plus metformin	Patients with inadequate glucose control on maximal doses of metformin	Parallel groups double-blind

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12 sulfonylurea G1

Trial	Treatments	Patients	Trials design and methods
glimepiride monotherapy vs metformin			
Charpentier , 2001 n=NA follow-up: 20 weeks	glimepiride monotherapy versus metformin monotherapy	Type 2 diabetic patients aged 35-70 years inadequately controlled by metformin monotherapy 2550 mg daily for at least 4 weeks	double-blind

References

Charpentier, 2001:

13 sulfonylurea G1 add on MET

Trial	Treatments	Patients	Trials design and methods
gliclazide vs nateglinide (add on MET)			
Ristic , 2006 n=NA follow-up: 52 weeks	gliclazide plus metformin versus nateglinide plus metformin	-	double-blind
gliclazide vs pioglitazone (add on MET)			
Matthews , 2005 n=313/317 follow-up: 52 weeks	gliclazide 80 mg o.d. (titrated up to 320 mg versus pioglitazone 15 mg o.d. (titrated up to 45 mg	Patients with poorly controlled type 2 diabetes	double-blind
glimepiride vs placebo (add on MET)			
LEAD-2 (Nauck) Sulf vs pbo , 2009 [NCT00318461] n=NA follow-up: 26 weeks	glimepiride (4 mg once daily). versus placebo	subjects previously treated with oral antidiabetes (OAD) therapy	double-blind
Charpentier , 2001 n=NA follow-up:	metformin and glimepiride versus metformin	Type 2 diabetic patients aged 35-70 years inadequately controlled by metformin monotherapy 2550 mg daily	double-blind France
glipizide GITS vs placebo (add on MET)			

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Trial	Treatments	Patients	Trials design and methods
Feinglos , 2005 n=61/61 follow-up: 16 weeks	2.5 mg glipizide GITS versus placebo	type 2 diabetes inadequately controlled (A1c 7-8.5%) on metformin (>or =1000 mg/day for >or =3 months)	double-blind
glibenclamide vs rosiglitazone (add on MET)			
Garber , 2006 n=NA follow-up: 24 weeks	metformin-glibenclamide 500/2.5 mg tablets (initial daily dose 1000/5 mg) versus metformin 500 mg plus rosiglitazone 4 mg (initial daily dose 1000-2000 mg + 4 mg, depending on previous treatment)	patients with type 2 diabetes inadequately controlled on metformin monotherapy	double-blind
gliclazide vs rosiglitazone (add on MET)			
Khanolkar , 2008 n=NA follow-up: 24 weeks	metformin and gliclazide versus metformin and rosiglitazone	-	
SU vs rosiglitazone (add on MET)			
Hamann , 2008 n=NA follow-up: 52 weeks	combination sulphonylurea plus metformin versus rosiglitazone/metformin fixed-dose combination	overweight individuals with inadequately controlled type 2 diabetes mellitus. Individuals with inadequate glycaemic control (HbA (1c)>or =7%) while on metformin monotherapy (>or =0.85 g/day)	
glipizide vs sitagliptin (add on MET)			
Nauck , 2007 n=NA follow-up: 52 weeks	glipizide versus sitagliptin	-	

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14 sulfonylureas G2

Trial	Treatments	Patients	Trials design and methods
vs			

continued...

Trial	Treatments	Patients	Trials design and methods
Cefalu , 1998 n=NA	-	-	
Hermann , 1994 n=NA	-	-	
Charpentier , 2001 n=NA	-	-	
glipizide vs glyburide			
Rosenstock , 1993 n=139 follow-up: 4 months	glipizide, 2.5 or 5 mg/day versus glyburide, 1.25 or 2.5 mg/day	elderly patients with NIDDM that was controlled for at least 3 months with oral sulfonylurea therapy	Parallel groups open
Birkeland , 1994 n=NA follow-up:	glipizide versus glyburide	NIDDM patients	
Birkeland , 1994 n=NA follow-up: 15 months	glipizide versus glyburide	NIDDM patients	Parallel groups double-blind
glipizide vs placebo			
Simonson , 1997 n=NA follow-up: 4+8 weeks	once-daily doses of 5, 20, 40, or 60 mg glipizide GITS versus placebo	NIDDM patients	Parallel groups double-blind
Testa , 1998 n=377/192 follow-up: 12 weeks	5 to 20 mg of glipizide gastrointestinal therapeutic system (GITS) versus placebo	patients with type 2 diabetes mellitus	Parallel groups USA
glyburide vs placebo			
Garber , 2002 n=NA follow-up:	glyburide 2.5 mg versus placebo	patients with type 2 diabetes who had failed diet and exercise	Parallel groups double-blind
Vray , 1995 n=NA follow-up:	glibenclamide (2.5 mg X 3/d) versus placebo	type 2 diabetic outpatients, 40-70 years of age, treated by diet alone or oral anti-diabetic drugs	Factorial plan double-blind China

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Testa, 1998:

Garber, 2002:

Vray, 1995:

15 sulfonylureas G2 add on MET

Trial	Treatments	Patients	Trials design and methods
glibenclamide vs c (add on MET)			
Hermann , 1991 n=NA follow-up: 6 months	metformin + glibenclamide versus metformin	patients with non-insulin-dependent diabetes mellitus	Parallel groups
glyburide vs c (add on MET)			
DeFronzo , 1995 n=NA follow-up: 29 weeks	metformin and glyburide versus metformin	patients with non-insulin-dependent diabetes mellitus	double-blind USA
Erle , 1999 n=NA follow-up:	low-dose glyburide plus metformin versus high-dose glyburide alone	-	Cross over
glibenclamide vs control (add on MET)			
Marre (ass) , 2002 n=NA follow-up: 16 weeks	metformin-glibenclamide 500 mg/2.5 mg or metformin-glibenclamide 500 mg/5 mg, titrated with the intention to achieve fasting plasma glucose (FPG) <or = 7 mmol/l versus metformin 500 mg,	patients with Type 2 diabetes mellitus inadequately controlled by metformin monotherapy	Parallel groups double-blind
Tosi , 2003 n=NA follow-up: 6 months	metformin 400 to 2,400 mg/d + glibenclamide 2.5 to 15 mg/d versus metformin (500 to 3,000 mg/d),	-	Cross over double-blind
glipizide vs control (add on MET)			
Goldstein n=NA follow-up:	glipizide/metformin 5/500 mg tablets versus metformin 500-mg	patients with type 2 DM that is uncontrolled by at least half the maximum labeled daily dose of a sulfonylurea	Cross over open
glyburide vs control (add on MET)			
Blonde , 2002 n=NA follow-up: 16 weeks	glyburide/metformin 2.5 mg/500 mg (n = 160); or glyburide/metformin 5 mg/500 mg (n = 162) versus metformin 500 mg	patients with inadequate glycaemic control on at least half-maximal dose of sulphonylurea	Parallel groups double-blind
Garber , 2003 n=NA follow-up:	glyburide/metformin versus metformin	patients with type 2 diabetes who had inadequate glycemic control [glycosylated hemoglobin A(1C) (A1C), >7% and <12%) with diet and exercise alone	Parallel groups

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Garber, 2003:

16 sulfonylureas G3 add on insulin

Trial	Treatments	Patients	Trials design and methods
glimepiride vs placebo (add on insulin)			
Riddle , 1994 <i>unpublished</i> n=72/73 follow-up:	Glimepiride (16 mg/day) plus insulin versus insulin plus placebo	obese patients with type 2 diabetes insufficiently controlled by full dosages of sulphonylureas (glimepiride titrated up to 8mg twice daily and with laboratory-monitored FPG of 10 to 16 mmol/L (180 to 300 mg/dl))	

References

Riddle, 1994:

17 sulfonylureas G3 add on MET

Trial	Treatments	Patients	Trials design and methods
glimepiride vs placebo (add on MET)			
LEAD-2 (Nauck) Sulf vs pbo , 2009 [NCT00318461] n=NA follow-up: 26 weeks	glimepiride (4 mg once daily). versus placebo	subjects previously treated with oral antidiabetes (OAD) therapy	double-blind
Charpentier , 2001 n=NA follow-up:	metformin and glimepiride versus metformin	Type 2 diabetic patients aged 35-70 years inadequately controlled by metformin monotherapy 2550 mg daily	double-blind France

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LEAD-2 (Nauck) Sulf vs pbo, 2009:

Charpentier, 2001:

18 sulfonylureas G3 monotherapy

Trial	Treatments	Patients	Trials design and methods
glimepiride vs placebo			
Kaneko , 1993 n=62/31 follow-up:	glimepiride 0.25mg od, 0.5mg od versus placebo	-	
Luis Bautista , 2003 n=NA follow-up: 14 weeks	glimepiride with titration to 2 mg and 4 mg for FPG levels >120 mg/dL versus placebo	Mexican American Patients with type 2 diabetes mellitus	Parallel groups double-blind Mexique
Rosenstock , 1996 n=416 follow-up: 14 weeks	glimepiride 8 mg q.d., 4 mg b.i.d., 16 mg q.d., or 8 mg b.i.d versus placebo	previously treated NIDDM patients	Parallel groups double-blind
Schade , 1998 n=123/126 follow-up:	glimepiride at individually determined optimal dose (1-8 mg of glimepiride) for 10+12 weeks versus placebo	patients with type 2 diabetes mellitus for whom diet therapy is unsuccessful	Parallel groups double-blind
Study 201 (Goldberg) , 1996 n=304 follow-up: 14 weeks	glimepiride, 1, 4, or 8 mg once daily versus placebo	patients with NIDDM	Parallel groups double-blind
Study 202 n=122/125 follow-up:	glimepiride 1-8mg od versus placebo	-	
glimepiride vs glibenclamide			
Draeger , 1996 n=524/520 follow-up:	glimepiride 1 mg daily versus 2.5 mg glibenclamide	type 2 diabetic patients stabilised on glibenclamide	Parallel groups double-blind
Protocol 311 n=427/425 follow-up:	glimepiride 1-8mg od versus glibenclamide 1.75-14 mg/day (od or bid)	-	
glimepiride vs gliclazide			
Charpentier (301F) n=96/107 follow-up:	glimepiride 1-4mg od versus gliclazide 80-320 mg/day (od or bid)	-	
glimepiride vs gliclazide or glibenclamide			

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Trial	Treatments	Patients	Trials design and methods
Inukai , 2005 n=172 follow-up: 6 months	glimepiride versus gliclazide or glibenclamide	Japanese type 2 diabetic patients (HbA1C >or = 7.0%), maintained on a conventional SU	Parallel groups open Japan
glimepiride od vs glimepiride bid			
Sonnenberg , 1997 n=50/48 follow-up:	glimepirid e6mg od versus glimepiride 3mg bid	-	Cross over
glimepiride vs glipizide			
Clark (301) , 1997 n=444/208 follow-up:	glimepiride 1-16 mg/day (od or bid) versus glipizide 2.5-40 mg/day (od or bid)	-	
glimepiride vs glyburide			
Dills , 1996 n=289/288 follow-up:	glimepiride 1-16mg od versus non-micronized glyburide 1.25-20mg od	patients with non-insulin dependent diabetes	Parallel groups double-blind

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