

Clinical trials of antidiabetic drugs for diabetes type 2 in patients inadequately controlled on monotherapy

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1 albiglutide

Trial	Treatments	Patients	Trials design and methods
albiglutide weekly vs placebo (add on MET)			
Rosenstock (30 mg weekly) , 2009 [NCT00518115] n=31/52 follow-up: 16 weeks	albiglutide 30mg weekly versus placebo	patients with type 2 diabetes inadequately controlled with diet and exercise or metformin monotherapy	Parallel groups double-blind US, Mexico, Chile, Dominical republic

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Rosenstock (30 mg weekly), 2009:

Rosenstock J, Reusch J, Bush M, Yang F, Stewart M, , Potential of albiglutide, a long-acting GLP-1 receptor agonist, in type 2 diabetes: a randomized controlled trial exploring weekly, biweekly, and monthly dosing. *Diabetes Care* 2009;32:1880-6. [[19592625](#)] [10.2337/dc09-0366](#)

2 bitherapy with MET

Trial	Treatments	Patients	Trials design and methods
dapagliflozin vs placebo (add on MET)			
Bailey (MB102014) , 2010 [NCT00528879] n=NA follow-up: 24 weeks	dapagliflozin (25 mg, n=137; 5 mg, n=137; or 10 mg, n=135) versus placebo	adults with type 2 diabetes who were receiving daily metformin (1500 mg per day) and had inadequate glycaemic control	Parallel groups double-blind

References

Bailey (MB102014), 2010:

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3 DPP-4 inhibitors

Trial	Treatments	Patients	Trials design and methods
linagliptin low dose vs linagliptin			
linagliptin 1218.62 <i>ongoing</i> [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
linagliptin + pioglitazone vs pioglitazone			
linagliptin 1264.3 <i>ongoing</i> [NCT01183013] n=NA follow-up: 30 weeks	linagliptin/pioglitazone (5/15, 5/30 and 5/45 mg) linagliptine versus pioglitazone	-	

References

linagliptin 1218.62, 0:

linagliptin 1264.3, 0:

4 DPP-4 inhibitors add on insulin

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

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Fonseca, 2007:

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

5 DPP-4 inhibitors add on MET

Trial	Treatments	Patients	Trials design and methods
linagliptin vs glimepiride (add on MET)			

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Trial	Treatments	Patients	Trials design and methods
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
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)			
linagliptin 1218.65 ongoing [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);	-	
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	

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Trial	Treatments	Patients	Trials design and methods
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
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
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
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)j	patients with type 2 diabetes inadequately controlled with metformin monotherapy	double-blind

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CV181-066, :

CV181-080, :

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6 DPP-4 inhibitors add on SU

Trial	Treatments	Patients	Trials design and methods
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

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7 DPP-4 inhibitors add on TZD

Trial	Treatments	Patients	Trials design and methods
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);	-	
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

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

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8 glucagon-like peptide analogs

Trial	Treatments	Patients	Trials design and methods
liraglutide other doses vs placebo			
NN2211-1799 <i>ongoing</i> [NCT00620282] n=NA follow-up: 3 months	liraglutide Stepwise dose increase, s.c. injection, once daily versus placebo	subjects with type 2 diabetes who are on diet and lifestyle changes or treated with metformin alon	double-blind USA
tasoglutide vs placebo			
BC21713 (vs placebo) <i>ongoing</i> [NCT00754988] n=NA follow-up:	tasoglutide (10mg once weekly or 10mg once weekly for 4 weeks followed by 20mg once weekly), versus placebo or sitagliptin 100mg once daily in addition to their continued prestudy metformin treatment	patients with type 2 diabetes mellitus inadequately controlled with metformin	parallel groups double-blind USA
tasoglutide 10mg once weekly vs placebo			
Nauck 10 once weekly vs PBO , 2009 [NCT00423501] n=257/49 follow-up: 12 weeks	tasoglutide, either 5, 10, or 20 mg once weekly or 10 or 20 mg once every 2 weeks for 8 weeks versus placebo	patients with type 2 diabetes inadequately controlled with metformin	Parallel groups double-blind
exenatide other doses vs placebo (add on MER+/-SU)			

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Trial	Treatments	Patients	Trials design and methods
Fineman , 2003 n=109 follow-up: 28 days	exenatide 3 regimen (0.08 micro g/kg) for 28 days versus placebo	patients with type 2 diabetes treated with diet and a sulfonylurea and/or metformin	Parallel groups double-blind USA
exenatide 10g/d vs placebo (add on MET)			
DeFronzo 10g/d , 2005 [NCT00039013] n=110/113 follow-up: 30 weeks	Exenatide 1020 g daily versus Placebo on-top of Metformin	patients with type 2 diabetes failing to achieve glycemic control with maximally effective metformin doses	Parallel groups double blind USA
exenatide 20g/d vs placebo (add on MET)			
DeFronzo 20g/d , 2005 [NCT00039013] n=NA follow-up: 30 weeks	Exenatide 1020 g daily versus Placebo on-top of Metformin	patients with type 2 diabetes failing to achieve glycemic control with maximally effective metformin doses	Parallel groups double blind USA
exenatide weekly vs placebo (add on MET)			
Kim , 2007 [NCT00103935] n=30/15 follow-up: 15 weeks	exenatide LAR 0.8 or 2 g daily versus Placebo on-top of metformin	subjects with type 2 diabetes suboptimally controlled with metformin and/or diet and exercise	Parallel groups double blind
liraglutide 1.8mg vs placebo (add on MET)			
LEAD-2 (Nauck) (1.8mg vs placebo) , 2009 [NCT00318461] n=242/122 follow-up: 26 weeks	Liraglutide 1.8 mg daily versus Placebo on-top of Metformin	subjects previously treated with oral antidiabetes therapy	Parallel groups double blind 21 countries
tasoglutide vs placebo (add on MET)			
Ratner (20mg once weekly) , 2010 [NCT00460941] n=97/32 follow-up: 8 weeks (+4wk)	tasoglutide s.c. 20mg once weekly for 8 weeks versus placebo s.c. once weekly on top metformin	subjects with Type 2 diabetes inadequately controlled on metformin alone	Parallel groups double-blind Australia, France, Germany, Mexico, Peru, USA
BC22092 ongoing [NCT00823992] n=NA follow-up:	tasoglutide (10mg sc once weekly for 4 weeks followed by 20mg once weekly) in addition to their prescribed, pre-existing metformin therapy versus placebo	obese patients with type 2 diabetes mellitus inadequately controlled with metformin monotherapy	parallel groups double-blind USA
exenatide 20g/d vs placebo (add on MET +/-SU)			
Gao , 2009 [NCT00324363] n=234/232 follow-up: 16 weeks	exenatide 5 mg then 10 mg twice-daily for 4 and 12 weeks versus placebo	Asian descent with type 2 diabetes and inadequate glycemic control taking metformin alone or Met and sulfonylureas	Parallel groups double-blind 4 countries
exenatide 10g/d vs placebo (add on SU)			

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Trial	Treatments	Patients	Trials design and methods
Buse 10g/d , 2004 [NCT00039026] n=125/123 follow-up: 30 weeks	Exenatide 5g twice daily versus Placebo on-top of SU	patients with type 2 diabetes failing maximally effective doses of a sulfonylurea as monotherapy	Parallel groups double blind (not adequate) US
exenatide 20g/d vs placebo (add on SU)			
Buse 20g/d , 2004 n=129/123 follow-up: 30 weeks	Exenatide 10g twice daily versus Placebo on-top of SU	patients with type 2 diabetes failing maximally effective doses of a sulfonylurea as monotherapy	double blind (not adequate) US
liraglutide 1.2mg vs placebo (add on SU)			
LEAD-1 SU (1.2 mg vs placebo) , 2009 [NCT00318422] n=228/115 follow-up: 26 weeks	Liraglutide 1.2 mg daily versus Placebo on-top of sulphonylureas	subjects with Type 2 diabetes	Parallel groups double-blind 21 countries
liraglutide 1.8mg vs placebo (add on SU)			
LEAD-1 SU (1.8 mg vs placebo) , 2009 [NCT00318422] n=234/114 follow-up: 26 weeks	Liraglutide 1.8 mg daily versus Placebo on-top of sulphonylureas	patients with type 2 diabetes	Parallel groups double-blind 21 countries
liraglutide other doses vs placebo (add on SU)			
NN2211-1701 ongoing [NCT00395746] n=NA follow-up: 24 weeks	liraglutide in combination with sulphonylurea versus placebo (add on to SU monotherapy)	subjects with type 2 diabetes	Parallel groups double-blind Japan
liraglutide 1.8mg vs placebo (add on SU+MET)			
LEAD-5 (vs placebo) , 2009 [NCT00331851] n=232/115 follow-up: 26 weeks	Liraglutide 1.8 mg daily versus Placebo on-top of sulphonylureas+metformin	adult patients with type 2 diabetes	Parallel groups double-blind 17 countries
liraglutide other doses vs sitagliptin (add on MET)			
MK-0431-403 ongoing [NCT01296412] n=NA follow-up:	Liraglutide + metformin versus Sitagliptin + metformin	patients with Type 2 Diabetes that is not adequately controlled with metformin alone	parallel groups open
exenatide before lunch and dinner vs exenatide before breakfast and dinner			
Exenatide Trial 10749 n=187/190 follow-up:	exenatide (10 g twice daily) administered subcutaneously before lunch and dinner versus exenatide (10 g twice daily) administered subcutaneously before breakfast and dinner	patients with type 2 Diabetes using oral antidiabetic therapy	Parallel groups open 2 countries
liraglutide other doses vs glibenclamide			

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Trial	Treatments	Patients	Trials design and methods
Seino , 2010 [NCT00393718] n=272/139 follow-up: 24-week	liraglutide 0.9 mg once daily versus glibenclamide once or twice daily at a planned maximum dose of 2.5 mg/day, before or after meals	Japanese subjects with type 2 diabetes, inadequately controlled with diet therapy or oral antidiabetic drug monotherapy	Parallel groups double-blind Japan
liraglutide 1.8mg vs glimepiride (add on MET)			
LEAD-2 (Nauck) (1.8 mg vs glimepiride) , 2009 [NCT00318461] n=242/244 follow-up: 26 weeks	Liraglutide 1.8 mg daily for 26 weeks versus Glimepiride on-top of Metformin	patients with type 3 diabetes previously treated with oral antidiabetes (OAD) therap	Parallel groups double blind 21 countries
exenatide other doses vs insulin glargine (add on MET/SU)			
Trial 8078 n=NA follow-up:	exenatide versus Insulin Glargine	Patients with Type 2 Diabetes Using Metformin or Sulfonylurea for Whom Insulin Is the Next Appropriate Therapy	
liraglutide 1.8mg vs insulin glargine (add on SU+MET)			
LEAD-5 (vs Glargine) , 2009 [NCT00331851] n=232/234 follow-up: 26 weeks	Liraglutide 1.8 mg daily versus Glargine on-top of sulphonylureas+metformin	adult patients with type 2 diabetes	Parallel groups open 17 countries
liraglutide other doses vs rosiglitazone (add on SU)			
LEAD-1 SU (1.8 vs rosiglitazone) , 2009 [NCT00318422] n=228/232 follow-up: 26 weeks	Liraglutide 0.6, 1.2 or 1.8 mg daily versus rosiglitazone on-top of sulphonylureas		Parallel groups double-blind 21 countries
liraglutide 1.2mg vs sitagliptin			
Pratley 1.2mg , 2010 [NCT00700817] n=225/219 follow-up: 26 weeks	liraglutide 1.2mg subcutaneously once daily versus oral sitagliptin 100mg once daily	patients with type 2 diabetes who did not have adequate glycemic control with metformin	Parallel groups open Europe, USA, Canada
liraglutide 1.8mg vs sitagliptin			
Pratley 1.8mg , 2010 [NCT00700817] n=221/219 follow-up: 26 weeks	liraglutide 1.8mg subcutaneously once daily versus oral sitagliptin 100mg once daily	patients with type 2 diabetes who did not have adequate glycemic control with metformin	Parallel groups open Europe, USA, Canada

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9 lixisenatide

Trial	Treatments	Patients	Trials design and methods
lixisenatide vs placebo (add on basal insulin)			
GETGOAL-L-ASIA <i>ongoing</i> [NCT00866658] n=NA follow-up: 24 weeks	24 weeks of AVE0010 versus placebo on Top of Basal Insulin +/- Sulfonylurea	Patients With Type 2 Diabetes Insufficiently Controlled With Basal Insulin With or Without Sulfonylurea	double-blind Japan
lixisenatide vs placebo (add on MET)			
Ratner DRI6012 , 2010 [NCT00299871] n=433/109 follow-up: 13 weeks	subcutaneous lixisenatide doses of 5, 10, 20 or 30 microg once daily or twice daily versus placebo	patients with Type 2 diabetes inadequately controlled with metformin (≥ 1000 mg/day)	Parallel groups double-blind (nature not volume) multinational
GETGOAL-M <i>ongoing</i> [NCT00712673] n=NA follow-up: 24 weeks	-	Type 2 diabetes mellitus insufficiently controlled with metformin	Parallel groups double-blind USA
lixisenatide vs sitagliptin (add on MET)			
EFC10780 , 2010 <i>ongoing</i> [NCT00976937] n=NA follow-up: 24 weeks	Lixisenatide titrated 15-20 g once daily versus Sitagliptin (add-on to Metformin)	Obese Type 2 Diabetic Patients Younger Than 50	Parallel groups double-blind WW

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GETGOAL-M, 0:

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10 meglitinides (glinides)

Trial	Treatments	Patients	Trials design and methods
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
mitiglinide vs placebo (on top pioglitazone)			

continued...

Trial	Treatments	Patients	Trials design and methods
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
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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11 sulfonylureas G2

Trial	Treatments	Patients	Trials design and methods
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
glyburide vs placebo			
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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12 sulfonylureas G2 add on MET

Trial	Treatments	Patients	Trials design and methods
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
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

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13 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))	

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14 sulfonylureas G3 add on MET

Trial	Treatments	Patients	Trials design and methods
glimepiride vs placebo (add on MET)			
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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15 sulfonylureas G3 monotherapy

Trial	Treatments	Patients	Trials design and methods
glimepiride vs gliclazide or glibenclamide			
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

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Inukai K, Watanabe M, Nakashima Y, Sawa T, Takata N, Tanaka M, Kashiwabara H, Yokota K, Suzuki M, Kurihara S, Awata T, Katayama S Efficacy of glimepiride in Japanese type 2 diabetic subjects. *Diabetes Res Clin Pract* 2005;68:250-7 [[15936468](#)] [10.1016/j.diabres.2004.10.002](#)

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Entry terms: glimeripide, glimepiride, glymepiride, HOE 490, HOE-490, Roname, Amaryl, Amarel, hydroxyglimepiride, hydroxy-glimepiride, , dapagliflozin, dapagliflozin, forxiga, BMS 512148, BMS512148, BMS-512148,

16 About TrialResults-center.org

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