

Clinical trials of insulin secretagogues - sulfonylureas for diabetes type 2 in all type of patients

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1 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:

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2 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

continued...

Trial	Treatments	Patients	Trials design and methods
glipizide GITS vs placebo (add on MET)			
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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3 sulfonylureas G2

33

Trial	Treatments	Patients	Trials design and methods
vs			
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			

continued...

Trial	Treatments	Patients	Trials design and methods
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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4 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)			

continued...

Trial	Treatments	Patients	Trials design and methods
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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5 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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6 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

References

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

Nauck M, Frid A, Hermansen K, Shah NS, Tankova T, Mitha IH, Zdravkovic M, Dring M, Matthews DR Efficacy and safety comparison of liraglutide, glimepiride, and placebo, all in combination with metformin, in type 2 diabetes: the LEAD (liraglutide effect and action in diabetes)-2 study. *Diabetes Care* 2009;32:84-90 [[18931095](#)] [10.2337/dc08-1355](#)

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7 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			
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			

continued...

Trial	Treatments	Patients	Trials design and methods
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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8 About TrialResults-center.org

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