

# Clinical trials of glimepiride

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## 1 diabetes type 2

Trial	Treatments	Patients	Trials design and methods
<b>glimepiride monotherapy vs metformin</b>			
<a href="#">Charpentier , 2001</a> 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
<b>glimepiride vs placebo</b>			
<a href="#">Kaneko , 1993</a> n=62/31 follow-up:	glimepiride 0.25mg od, 0.5mg od versus placebo	-	
<a href="#">Luis Bautista , 2003</a> 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
<a href="#">Rosenstock , 1996</a> 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
<a href="#">Schade , 1998</a> 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
<a href="#">Study 201 (Goldberg) , 1996</a> n=304 follow-up: 14 weeks	glimepiride, 1, 4, or 8 mg once daily versus placebo	patients with NIDDM	Parallel groups double-blind
<a href="#">Study 202</a> n=122/125 follow-up:	glimepiride 1-8mg od versus placebo	-	
<b>glimepiride vs placebo (add on insulin)</b>			

continued...

Trial	Treatments	Patients	Trials design and methods
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unpublished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))	
<b>glimepiride vs placebo (add on MET)</b>			
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
<b>glimepiride vs glibenclamide</b>			
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)	-	
<b>glimepiride vs gliclazide</b>			
Charpentier (301F) n=96/107 follow-up:	glimepiride 1-4mg od versus gliclazide 80-320 mg/day (od or bid)	-	
<b>glimepiride vs gliclazide or glibenclamide</b>			
Inukai , 2005 n=172 follow-up: 6 months	glimepiride versus gliclazide or glibenclamide	Japanese type 2 diabetic patients (HbA1C $\geq$ 7.0% ), maintained on a conventional SU	Parallel groups open Japan
<b>dapagliflozin + Glimepiride vs glimepiride</b>			
Strojek , 2011 [NCT00680745] n=NA follow-up:	Dapagliflozin in Comb.With Glimepiride versus glimepiride alone	Type2 Diab.Who Have Inadeq. Glycaemic Control on Glimepiride Therapy Alone	
<b>glimepiride od vs glimepiride bid</b>			

continued...

Trial	Treatments	Patients	Trials design and methods
Sonnenberg , 1997 n=50/48 follow-up:	glimepirid e6mg od versus glimepiride 3mg bid	-	Cross over
<b>glimepiride vs glipizide</b>			
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)	-	
<b>glimepiride vs glyburide</b>			
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

More details and results :

- antidiabetic drugs for diabetes type 2 in all types of patients at <http://www.trialresultscenter.org/go-Q81>
- insulin secretagogues for diabetes type 2 in all type of patients at <http://www.trialresultscenter.org/go-Q409>
- SGLT2 inhibitors for diabetes type 2 in all type of patients at <http://www.trialresultscenter.org/go-Q479>
- insulin secretagogues - sulfonylureas for diabetes type 2 in all type of patients at <http://www.trialresultscenter.org/go-Q483>
- antidiabetic drugs for diabetes type 2 in patients inadequately controlled on metformin at <http://www.trialresultscenter.org/go-Q509>
- antidiabetic drugs for diabetes type 2 in patients inadequately controlled on monotherapy at <http://www.trialresultscenter.org/go-Q512>

## References

### Charpentier, 2001:

Charpentier G, Fleury F, Kabir M, Vaur L, Halimi S Improved glycaemic control by addition of glimepiride to metformin monotherapy in type 2 diabetic patients. Diabet Med 2001;18:828-34 [[11678974](#)]

### Kaneko, 1993:

Kaneko T, Kaku K, Sakamoto N, et al. Study on minimum effective dose of glimepiride (HOE490) for non-insulin dependent diabetes mellitus patients. Multi center double blind trial compared to placebo [in Japanese] Rinsho Iyaku 1993; 9 (4): 827-48

### Luis Bautista, 2003:

Luis Bautista J, Bugos C, Dirnberger G, Atherton T Efficacy and safety profile of glimepiride in Mexican American Patients with type 2 diabetes mellitus: a randomized, placebo-controlled study. Clin Ther 2003;25:194-209 [[12637120](#)]

**Rosenstock, 1996:**

Rosenstock J, Samols E, Muchmore DB, Schneider J Glimepiride, a new once-daily sulfonylurea. A double-blind placebo-controlled study of NIDDM patients. Glimepiride Study Group. Diabetes Care 1996;19:1194-9 [[8908379](#)]

**Schade, 1998:**

Schade DS, Jovanovic L, Schneider J A placebo-controlled, randomized study of glimepiride in patients with type 2 diabetes mellitus for whom diet therapy is unsuccessful. J Clin Pharmacol 1998;38:636-41 [[9702849](#)]

**Study 201 (Goldberg), 1996:**

Goldberg RB, Holvey SM, Schneider J A dose-response study of glimepiride in patients with NIDDM who have previously received sulfonylurea agents. The Glimepiride Protocol 201 Study Group. Diabetes Care 1996;19:849-56 [[8842603](#)]

**Study 202, :**

Hoechst-Roussel Pharmaceuticals Inc. USA. A placebo controlled, dose-titration study of HOE490 in patients with noninsulin- dependent diabetes mellitus (NIDDM) Protocol 202.

**Riddle, 1994:**

unpublished

Riddle M, Schneider J, Glimepiride CG. Glimepiride (HOE490) combined with insulin for NIDDM secondary failures to sulfonylurea monotherapy: results of a multicenter trial [abstract]. 15th Int Diab Fed Congr 1994: 418

**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](#)

**Charpentier, 2001:**

Charpentier G, Fleury F, Kabir M, Vaur L, Halimi S Improved glycaemic control by addition of glimepiride to metformin monotherapy in type 2 diabetic patients. Diabet Med 2001;18:828-34 [[11678974](#)]

Charpentier G, Fleury F, Kabir M, Vaur L, Halimi S, Improved glycaemic control by addition of glimepiride to metformin monotherapy in type 2 diabetic patients. Diabet Med 2001;18:828-34. [[11678974](#)]

**Draeger, 1996:**

Draeger KE, Wernicke-Panten K, Lomp HJ, Schler E, Roskamp R Long-term treatment of type 2 diabetic patients with the new oral antidiabetic agent glimepiride (Amaryl): a double-blind comparison with glibenclamide. Horm Metab Res 1996;28:419-25 [[8911976](#)] [10.1055/s-2007-979830](#)

Draeger KE, Wernicke-Panten K, Lomp HJ, Schler E, Roskamp R, Long-term treatment of type 2 diabetic patients with the new oral antidiabetic agent glimepiride (Amaryl): a double-blind comparison with glibenclamide. Horm Metab Res 1996;28:419-25. [[8911976](#)] [10.1055/s-2007-979830](#)

**Protocol 311, :**

Draeger E, Roskamp R, Lomp H-J, et al. Multicenter clinical trial to study the effects of glimepiride during long-term treatment of type II diabetic patients; double-blind, parallel-group comparison of glimepiride and Euglucon N (micronised glibenclamide). Protocol 311. Hoechst AG.

**Charpentier (301F), :**

Charpentier G. Comparative double-blind study of the effective dosages of glimepiride and gliclazide in non-insulin-dependent diabetics Protocol 301F. Laboratoires Hoechst, France

**Inukai, 2005:**

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](#)

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](#)

**Strojek, 2011:**

Strojek K, Yoon KH, Hrubá V, Elze M, Langkilde AM, Parikh S Effect of dapagliflozin in patients with type 2 diabetes who have inadequate glycaemic control with glimepiride: a randomized, 24-week, double-blind, placebo-controlled trial. *Diabetes Obes Metab* 2011;13:928-38 [[21672123](#)] [10.1111/j.1463-1326.2011.01434.x](#)

Kohan DE, Fioretto P, Johnsson K, Parikh S, Ptaszynska A, Ying L The effect of dapagliflozin on renal function in patients with type 2 diabetes. *J Nephrol* 2016;: [[26894924](#)]

Strojek K, Yoon KH, Hrubá V, Elze M, Langkilde AM, Parikh S [Effect of dapagliflozin in patients with type 2 diabetes who have inadequate glycaemic control with glimepiride]. *Dtsch Med Wochenschr* 2013;138 Suppl 1:S16-26 [[23529567](#)]

**Sonnenberg, 1997:**

Sonnenberg GE, Garg DC, Weidler DJ, Dixon RM, Jaber LA, Bowen AJ, DeChemey GS, Mullican WS, Stonesifer LD Short-term comparison of once- versus twice-daily administration of glimepiride in patients with non-insulin-dependent diabetes mellitus. *Ann Pharmacother* 1997;31:671-6 [[9184703](#)]

**Clark (301), 1997:**

Clark Jr CM, Goldberg RB. Glimepiride dosing and efficacy: results of placebo-controlled, dose-regimen, and active-controlled trials *Postgrad Med* 1997 Jun Special Report: 45-56

**Dills, 1996:**

Dills DG, Schneider J Clinical evaluation of glimepiride versus glyburide in NIDDM in a double-blind comparative study. Glimepiride/Glyburide Research Group. *Horm Metab Res* 1996;28:426-9 [[8911977](#)] [10.1055/s-2007-979831](#)

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