

Clinical trials of antidiabetic drugs for diabetes type 2 in all types of patients

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1 insulin therapy

Trial	Treatments	Patients	Trials design and methods
insulin vs control			
UGDP n=414/205 follow-up:	-	-	
UKPDS 33 n=911/896 follow-up:	-	-	

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UGDP, :

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UKPDS 33, :

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2 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			

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Trial	Treatments	Patients	Trials design and methods
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
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			

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Trial	Treatments	Patients	Trials design and methods
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
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			

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Trial	Treatments	Patients	Trials design and methods
CDJN608AUS13 n=NA	-	-	
CDJN608AUS13 n=NA	-	-	
CDJN608A ES03 <i>unpublished</i> n=NA follow-up:	-	-	
NAVIGATOR n=NA follow-up:	-	patients with impaired glucose tolerance (IGT)	
Schwarz , 2008 n=66 follow-up: 12 weeks	nateglinide monotherapy (120 mg, before meals) versus placebo	drug-naïve 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-naïve patients with T2DM aged ≥65 years	double-blind
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

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Trial	Treatments	Patients	Trials design and methods
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)			
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

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Trial	Treatments	Patients	Trials design and methods
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
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)			

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Trial	Treatments	Patients	Trials design and methods
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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3 sulfonylureas G2

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

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Trial	Treatments	Patients	Trials design and methods
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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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)			

continued...

Trial	Treatments	Patients	Trials design and methods
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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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)			
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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7 sulfonylureas G3 monotherapy

Trial	Treatments	Patients	Trials design and methods
glimepiride vs placebo			

continued...

Trial	Treatments	Patients	Trials design and methods
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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