

Clinical trials of nateglinide

TrialResults-center www.trialresultscenter.org

1 diabetes type 2

Trial	Treatments	Patients	Trials design and methods
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
nateglinide vs glyburide (add on MET)			
PRESERVE-beta n=NA follow-up:	-	-	-
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	-	-
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unpublished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-nave patients with T2DM aged >or=65 years	double-blind

continued...

Trial	Treatments	Patients	Trials design and methods
Schwarz (study 2) , 2008 n=NA follow-up: 12 weeks	nateglinide monotherapy (120 mg, before meals) versus placebo	drug-naïve patients with T2DM aged >or=65 years	double-blind
NAVIGATOR nateglinide , 2010 [NCT00097786] n=4645/4661 follow-up: 5 years	nateglinide 60mg 3 times daily versus placebo	subjects with impaired glucose tolerance and either CV disease or CV risk factors	Factorial plan double-blind 40 countries
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
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)			

continued...

Trial	Treatments	Patients	Trials design and methods
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
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 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
nateglinide vs placebo (add on TZD)			
026-CL-004 <i>ongoing</i> [NCT00189774] n=NA follow-up:	nateglinide versus placebo (on top pioglytazone)	inadequately controlled type 2 diabetic patients with pioglitazone treatment	double-blind Japan
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

More details and results :

- antidiabetic drugs for diabetes type 2 in all types of patients at <http://www.trialresultscenter.org/go-Q81>
- prevention for diabetes type 2 in all type of patients at <http://www.trialresultscenter.org/go-Q341>
- insulin secretagogues for diabetes type 2 in all type of patients at <http://www.trialresultscenter.org/go-Q409>
- prevention for diabetes type 2 in people with impaired glucose tolerance at <http://www.trialresultscenter.org/go-Q416>
- 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>
- insulin secretagogues - Meglitinides (glinides) for diabetes type 2 in all types of patients at <http://www.trialresultscenter.org/go-Q549>

References

Derosa , 2009:

Derosa G, D'Angelo A, Fogari E, Salvadeo S, Gravina A, Ferrari I, Cicero AF Nateglinide and glibenclamide metabolic effects in nave type 2 diabetic patients treated with metformin. J Clin Pharm Ther 2009;34:13-23 [19125899] 10.1111/j.1365-2710.2008.00984.x

Derosa G, D'Angelo A, Fogari E, Salvadeo S, Gravina A, Ferrari I, Cicero AF Effects of nateglinide and glibenclamide on prothrombotic factors in nave type 2 diabetic patients treated with metformin: a 1-year, double-blind, randomized clinical trial. Intern Med 2007;46:1837-46 [18025765]

PRESERVE-beta, :

Gerich J, Raskin P, Jean-Louis L, Purkayastha D, Baron MA PRESERVE-beta: two-year efficacy and safety of initial combination therapy with nateglinide or glyburide plus metformin. Diabetes Care 2005;28:2093-9 [16123472]

Horton DOUBLON, 2000:

Horton ES, Foley JE, Shen SG, Baron MA Efficacy and tolerability of initial combination therapy with nateglinide and metformin in treatment-naive patients with type 2 diabetes. Curr Med Res Opin 2004;20:883-9 [15200747] 10.1185/030079903125003881

Horton ES, Clinkingbeard C, Gatlin M, Foley J, Mallows S, Shen S Nateglinide alone and in combination with metformin improves glycemic control by reducing mealtime glucose levels in type 2 diabetes. Diabetes Care 2000;23:1660-5 [11092289]

CDJN608AUS13 , :

CDJN608AUS13 , :

CDJN608A ES03, :

unpublished

NAVIGATOR, :

Holman RR, Haffner SM, McMurray JJ, Bethel MA, Holzhauer B, Hua TA, Belenkov Y, Boolell M, Buse JB, Buckley BM, Chacra AR, Chiang FT, Charbonnel B, Chow CC, Davies MJ, Deedwania P, Diem P, Einhorn D, Fonseca V, Fulcher GR, Gaciong Z, Gaztambide S, Giles T Effect of nateglinide on the incidence of diabetes and cardiovascular events. N Engl J Med 2010 Apr 22;362:1463-76 [20228402] 10.1056/NEJMoa1001122

Califf RM, Boolell M, Haffner SM, Bethel MA, McMurray J, Duggal A, Holman RR Prevention of diabetes and cardiovascular disease in patients with impaired glucose tolerance: rationale and design of the Nateglinide And Valsartan in Impaired Glucose Tolerance Outcomes Research (NAVIGATOR) Trial. Am Heart J 2008;156:623-32 [18946890]

Schwarz , 2008:

Schwarz SL, Gerich JE, Marcellari A, Jean-Louis L, Purkayastha D, Baron MA Nateglinide, alone or in combination with metformin, is effective and well tolerated in treatment-naive elderly patients with type 2 diabetes. Diabetes Obes Metab 2008;10:652-60 [17941876] 10.1111/j.1463-1326.2007.00792.x

Schwarz (study 2), 2008:

Schwarz SL, Gerich JE, Marcellari A, Jean-Louis L, Purkayastha D, Baron MA Nateglinide, alone or in combination with metformin, is effective and well tolerated in treatment-naive elderly patients with type 2 diabetes. *Diabetes Obes Metab* 2008;10:652-60 [[17941876](#)] [10.1111/j.1463-1326.2007.00792.x](#)

NAVIGATOR nateglinide, 2010:

Effect of Nateglinide on the Incidence of Diabetes and Cardiovascular Events. *N Engl J Med* 2010 Mar 14;: [[20228402](#)] [10.1056/NEJMoa1001122](#)

Hanefeld, 1990:

Hanefeld M, Bouter KP, Dickinson S, Guitard C Rapid and short-acting mealtime insulin secretion with nateglinide controls both prandial and mean glycemia. *Diabetes Care* 2000;23:202-7 [[10868832](#)]

Horton, 2000:

Horton ES, Clinkingbeard C, Gatlin M, Foley J, Mallows S, Shen S Nateglinide alone and in combination with metformin improves glycemic control by reducing mealtime glucose levels in type 2 diabetes. *Diabetes Care* 2000;23:1660-5 [[11092289](#)]

Mari, 2005:

Mari A, Gastaldelli A, Foley JE, Pratley RE, Ferrannini E Beta-cell function in mild type 2 diabetic patients: effects of 6-month glucose lowering with nateglinide. *Diabetes Care* 2005;28:1132-8 [[15855578](#)]

Marre, 2002:

Marre M, Van Gaal L, Usadel KH, Ball M, Whatmough I, Guitard C Nateglinide improves glycaemic control when added to metformin monotherapy: results of a randomized trial with type 2 diabetes patients. *Diabetes Obes Metab* 2002;4:177-86 [[12047396](#)]

Moses, 2001:

Moses RG, Gomis R, Frandsen KB, Schlienger JL, Dedov I Flexible meal-related dosing with repaglinide facilitates glycemic control in therapy-naive type 2 diabetes. *Diabetes Care* 2001;24:11-5 [[11194214](#)]

Saloranta, 2002:

Saloranta C, Hershon K, Ball M, Dickinson S, Holmes D Efficacy and safety of nateglinide in type 2 diabetic patients with modest fasting hyperglycemia. *J Clin Endocrinol Metab* 2002;87:4171-6 [[12213867](#)]

Dashora , 2007:

Dashora UK, Sibal L, Ashwell SG, Home PD Insulin glargine in combination with nateglinide in people with Type 2 diabetes: a randomized placebo-controlled trial. *Diabet Med* 2007;24:344-9 [[17298589](#)] [10.1111/j.1464-5491.2007.02094.x](#)

Juurinen , 2009:

Juurinen L, Tiikkainen M, Saltevo J, Nikkil K, Lanki H, Leppvuori E, Kock T, Teikari-Myyr T, Kauppinen-Mkelin R, Kotronen A, Yki-Jrvinen H Nateglinide combination therapy with basal insulin and metformin in patients with Type 2 diabetes. *Diabet Med* 2009;26:409-15 [[19388972](#)] [10.1111/j.1464-5491.2009.02691.x](#)

NCT00402909, :

Rosenstock , 2004:

Rosenstock J, Hassman DR, Madder RD, Brazinsky SA, Farrell J, Khutoryansky N, Hale PM Repaglinide versus nateglinide monotherapy: a randomized, multicenter study. *Diabetes Care* 2004;27:1265-70 [[15161773](#)]

Li, 2009:

Li C, Xia J, Zhang G, Wang S, Wang L Nateglinide versus repaglinide for type 2 diabetes mellitus in China. *Acta Diabetol* 2009 Dec;46:325-33 [[19183841](#)]

Li, 2007:

Li J, Tian H, Li Q, Wang N, Wu T, Liu Y, Ni Z, Yu H, Liang J, Luo R, Li Y, Huang L Improvement of insulin sensitivity and beta-cell function by nateglinide and repaglinide in type 2 diabetic patients - a randomized controlled double-blind and double-dummy multicentre clinical trial. *Diabetes Obes Metab* 2007 Jul;9:558-65 [17587398]

026-CL-004, 0:

ongoing trial NCT00189774

Ristic, 2006:

Ristic S, Collober-Maugeais C, Pecher E, Cressier F Comparison of nateglinide and gliclazide in combination with metformin, for treatment of patients with Type 2 diabetes mellitus inadequately controlled on maximum doses of metformin alone. *Diabet Med* 2006;23:757-62 [16842480] 10.1111/j.1464-5491.2006.01914.x

Ristic S, Collober-Maugeais C, Cressier F, Tang P, Pecher E Nateglinide or gliclazide in combination with metformin for treatment of patients with type 2 diabetes mellitus inadequately controlled on maximum doses of metformin alone: 1-year trial results. *Diabetes Obes Metab* 2007;9:506-11 [17587393] 10.1111/j.1463-1326.2006.00632.x

2 impaired fasting glucose

Trial	Treatments	Patients	Trials design and methods
nateglinide vs placebo			
NAVIGATOR nateglinide , 2010 [NCT00097786] n=4645/4661 follow-up: 5 years	nateglinide 60mg 3 times daily versus placebo	subjects with impaired glucose tolerance and either CV disease or CV risk factors	Factorial plan double-blind 40 countries

More details and results :

- prevention for impaired fasting glucose in all type of patients at <http://www.trialresultscenter.org/go-Q342>

References

NAVIGATOR nateglinide, 2010:

Effect of Nateglinide on the Incidence of Diabetes and Cardiovascular Events. *N Engl J Med* 2010 Mar 14;: [20228402] 10.1056/NEJMoa1001122

Entry terms: nateglinide, nate-glinide, senaglinide, IPCCPA, AY 4166, AY-4166, DJN 608, Starsis, Starlix, Novartis brand of nateglinide, A 4166, A-4166, Fastic,