Clinical trials of glargine

TrialResults-center www.trialresultscenter.org

1 diabetes type 2

Trial	Treatments	Patients	Trials design and methods
glargine vs			
Eliaschewitz n=231/250 follow-up: 24 weeks	-	-	
Fonseca n=52/48 follow-up: 28 weeks	-	-	
Massi n=293/285 follow-up: 52 weeks	-	-	
Pan n=220/223 follow-up: 24 weeks	-	-	
Philis-Tsimikas n=334/164 follow-up: 20 weeks	-	-	
Rosenstock n=259/259 follow-up: 28 weeks	-	-	
Wang n=16/8 follow-up: 12 weeks	-	-	
Yki-Yarvinen n=214/208 follow-up: 52 weeks	-	-	
Yki-Yarvinen n=61/49 follow-up: 36 weeks	-	-	
Yokoyama n=31/31 follow-up: 26 weeks	-	-	
morning insulin glargine vs bedtime insulin glargine			

continued...

Trial	Treatments	Patients	Trials design and methods
Fritche n=463/232 follow-up: 24 weeks	morning insulin glargine versus bedtime insulin glargine	patients with type 2 diabetes previously treated with oral antidiabetic agents	open
lispro +glargine vs continuous infusion			
Herman , 2005 n=NA follow-up:	multiple daily injection using insulin lispro and insulin glargine versus continuous subcutaneous insulin infusion using insulin lispro	-	
insulin glargine vs control			
ORIGINE , 2012 [NCT00069784] n=6264/6273 follow-up: 6.2 years	insulin glargine (with a target fasting blood glucose level of 95 mg per deciliter versus standard care	with cardiovascular risk factors plus impaired fasting glucose, impaired glucose tolerance, or type 2 diabetes	
insulin glulisine + glargine vs glargine once daily			
Owens , 2011 n=49/57 follow-up: 3 months	basal+bolus (single dose of insulin glulisine immediately prior to the main meal) versus basal insulin (glargin)	patients withT2DM using any basal insulin and HbA1c >7.0% after 3-month of insulin glargine titrated to optimize fasting bloodglucose control	Parallel groups open-label US, UK, Russia
glulisine + glargine vs glulisine + glargine			
OPAL , 2008 n=NA follow-up:	single injection of glulisine before breakfast versus single injection of glulisine before their main mealtime (breakfast, lunch or dinner);	patients with type 2 diabetes who were suboptimally controlled on their previous glargine and OAD regimen	
glargine vs NPH			
Riddle POC 4002 Glargine , 2003 n=NA follow-up:	bedtime glargine versus NPH once daily	overweight men and women with inadequate glycemic control (HbA(1c) >7.5%) on one or two oral agents	Parallel groups open-label
HOE 901/3002 , 2000 n=NA follow-up:	bedtime insulin glargine versus bedtime NPH insulin	insulin-naive type 2 diabetic patients with poor glycemic control on oral antidiabetic agents	
glargine vs NPH + SU			
Riddle n=367/389 follow-up: 24 weeks	bedtime glargine versus NPH	overweight men and women with inadequate glycemic control (HbA(1c) >7.5%) on one or two oral agents	open

continued...

Trial	Treatments	Patients	Trials design and methods
insulin glargine vs placebo			
GRACE - ORIGIN (glargine) , 2012 n=1184 follow-up:	insulin glargine (with a target fasting blood glucose level of <=95 mg per deciliter [5.3 mmol per liter]) versus standard glycemic care alone	subject with known CV disease and/or CV risk factors plus impaired fasting glucose, impaired glucose tolerance, or type 2 diabetes	Factorial plan open-label
insulin glargine plus insulin glulisine vs premixed insulin analogues			
Levin , 2011 n=NA	-	-	

More details and results :

- prevention for diabetes type 2 in all type of patients at http://www.trialresultscenter.org/go-Q341
- prevention for diabetes type 2 in people with impaired glucose tolerance at http://www.trialresultscenter.org/go-Q416
- intensive therapy for diabetes type 2 in all type of patients at http://www.trialresultscenter.org/go-Q459
- insulin therapy for diabetes type 2 in all type of patients at http://www.trialresultscenter.org/go-Q548
- glucose lowering for cardiovascular prevention for diabetes type 2 in all type of patients at http://www.trialresultscenter.org/go-Q576

References

Eliaschewitz , :

Eliaschewitz FG, Calvo C, Valbuena H, Ruiz M, Aschner P, Villena J, Ramirez LA, Jimenez J Therapy in type 2 diabetes: insulin glargine vs. NPH insulin both in combination with glimepiride. Arch Med Res 2006;37:495-501 [16715577]

Fonseca , :

Fonseca V, Bell DS, Berger S, Thomson S, Mecca TE A comparison of bedtime insulin glargine with bedtime neutral protamine hagedorn insulin in patients with type 2 diabetes: subgroup analysis of patients taking once-daily insulin in a multicenter, randomized, parallel group study. Am J Med Sci 2004;328:274-80 [15545844]

Massi , :

Massi Benedetti M, Humburg E, Dressler A, Ziemen M A one-year, randomised, multicentre trial comparing insulin glargine with NPH insulin in combination with oral agents in patients with type 2 diabetes. Horm Metab Res 2003;35:189-96 [12734781] 10.1055/s-2003-39080

Pan , :

Pan CY, Sinnassamy P, Chung KD, Kim KW Insulin glargine versus NPH insulin therapy in Asian Type 2 diabetes patients. Diabetes Res Clin Pract 2007;76:111-8 [17011662] 10.1016/j.diabres.2006.08.012

Philis-Tsimikas , :

Philis-Tsimikas A, Charpentier G, Clauson P, Ravn GM, Roberts VL, Thorsteinsson B Comparison of once-daily insulin detemir with NPH insulin added to a regimen of oral antidiabetic drugs in poorly controlled type 2 diabetes. Clin Ther 2006;28:1569-81 [17157113] 10.1016/j.clinthera.2006.10.020

Rosenstock , :

Rosenstock J, Davies M, Home PD, Larsen J, Koenen C, Schernthaner G A randomised, 52-week, treat-to-target trial comparing insulin detemir with insulin glargine when administered as add-on to glucose-lowering drugs in insulin-naive people with type 2 diabetes. Diabetologia 2008;51:408-16 [18204830] 10.1007/s00125-007-0911-x

Wang , :

Wang XL, Lu JM, Pan CY, Mu YM, Dou JT, Ba JM, Wang X Evaluation of the superiority of insulin glargine as basal insulin replacement by continuous glucose monitoring system. Diabetes Res Clin Pract 2007;76:30-6 [16979255] 10.1016/j.diabres.2006.08.005

Yki-Yarvinen , :

Yki-Jrvinen H, Juurinen L, Alvarsson M, Bystedt T, Caldwell I, Davies M, Lahdenper S, Nijpels G, Vhtalo M Initiate Insulin by Aggressive Titration and Education (INITIATE): a randomized study to compare initiation of insulin combination therapy in type 2 diabetic patients individually and in groups. Diabetes Care 2007;30:1364-9 [17384341] 10.2337/dc06-1357

Yki-Yarvinen , :

Yki-Jrvinen H, Dressler A, Ziemen M Less nocturnal hypoglycemia and better post-dinner glucose control with bedtime insulin glargine compared with bedtime NPH insulin during insulin combination therapy in type 2 diabetes. HOE 901/3002 Study Group. Diabetes Care 2000;23:1130-6 [10937510]

Yokoyama, :

Yokoyama H, Tada J, Kamikawa F, Kanno S, Yokota Y, Kuramitsu M Efficacy of conversion from bedtime NPH insulin to morning insulin glargine in type 2 diabetic patients on basal-prandial insulin therapy. Diabetes Res Clin Pract 2006;73:35-40 [16513202] 10.1016/j.diabres.2005.12.009

Fritche , :

Fritsche A, Schweitzer MA, Hring HU Glimepiride combined with morning insulin glargine, bedtime neutral protamine hagedorn insulin, or bedtime insulin glargine in patients with type 2 diabetes. A randomized, controlled trial. Ann Intern Med 2003;138:952-9 [12809451]

Herman, 2005:

Herman WH, Ilag LL, Johnson SL, Martin CL, Sinding J, Al Harthi A, Plunkett CD, LaPorte FB, Burke R, Brown MB, Halter JB, Raskin P A clinical trial of continuous subcutaneous insulin infusion versus multiple daily injections in older adults with type 2 diabetes. Diabetes Care 2005;28:1568-73 [15983302]

ORIGINE, 2012:

Gerstein HC, Bosch J, Dagenais GR, Daz R, Jung H, Maggioni AP, Pogue J, Probstfield J, Ramachandran A, Riddle MC, Rydn LE, Yusuf S Basal insulin and cardiovascular and other outcomes in dysglycemia. N Engl J Med 2012;367:319-28 [22686416]

Owens, 2011:

Owens DR, Luzio SD, Sert-Langeron C, Riddle MC Effects of initiation and titration of a single pre-prandial dose of insulin glulisine while continuing titrated insulin glargine in type 2 diabetes: a 6-month 'proof-of-concept' study. Diabetes Obes Metab 2011;13:1020-7 [21679291] 10.1111/j.1463-1326.2011.01459.x

OPAL, 2008:

Lankisch MR, Ferlinz KC, Leahy JL, Scherbaum WA Introducing a simplified approach to insulin therapy in type 2 diabetes: a comparison of two single-dose regimens of insulin glulisine plus insulin glargine and oral antidiabetic drugs. Diabetes Obes Metab 2008 Dec;10:1178-85 [19040645] 10.1111/j.1463-1326.2008.00967.x

Riddle POC 4002 Glargine, 2003:

Riddle MC, Rosenstock J, Gerich J The treat-to-target trial: randomized addition of glargine or human NPH insulin to oral therapy of type 2 diabetic patients. Diabetes Care 2003;26:3080-6 [14578243]

HOE 901/3002, 2000:

Yki-Jrvinen H, Dressler A, Ziemen M Less nocturnal hypoglycemia and better post-dinner glucose control with bedtime insulin glargine compared with bedtime NPH insulin during insulin combination therapy in type 2 diabetes. HOE 901/3002 Study Group. Diabetes Care 2000;23:1130-6 [10937510]

Riddle , :

Riddle MC, Rosenstock J, Gerich J The treat-to-target trial: randomized addition of glargine or human NPH insulin to oral therapy of type 2 diabetic patients. Diabetes Care 2003;26:3080-6 [14578243]

GRACE - ORIGIN (glargine), 2012:

Levin, 2011:

Levin PA, Zhang Q, Mersey JH, Lee FY, Bromberger LA, Bhushan M, Bhushan R, Glycemic control with insulin glargine plus insulin glulisine versus premixed insulin analogues in real-world practices: a cost-effectiveness study with a randomized pragmatic trial design. Clin Ther 2011;33:841-50. [21719107] 10.1016/j.clinthera.2011.05.091

2 impaired fasting glucose

Trial	Treatments	Patients	Trials design and methods
insulin glargine vs placebo			
GRACE - ORIGIN (glargine) , 2012 n=1184 follow-up:	insulin glargine (with a target fasting blood glucose level of <=95 mg per deciliter [5.3 mmol per liter]) versus standard glycemic care alone	subject with known CV disease and/or CV risk factors plus impaired fasting glucose, impaired glucose tolerance, or type 2 diabetes	Factorial plan open-label

More details and results :

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

References

GRACE - ORIGIN (glargine), 2012: