

Clinical trials of saxagliptin

TrialResults-center www.trialresultscenter.org

1 diabetes type 2

Trial	Treatments	Patients	Trials design and methods
saxagliptin vs			
Fonseca , 2012 [NCT00960076] n=NA follow-up:	-	-	
Forst , 2011 n=NA	-	-	
Gke , 2010 n=NA follow-up:	-	-	
Kawamori , 2012 [NCT00654381] n=NA follow-up:	-	-	
Nowicki , 2011 [NCT00614939] n=NA follow-up:	-	-	
Nowicki , 2011 [NCT00614939] n=NA follow-up:	-	-	
Scheen , 2010 n=NA	-	-	
Stenlf , 2010 n=NA	-	-	
Yang , 2011 [NCT00661362] n=NA follow-up:	-	-	
saxagliptin + glyburide vs glyburide uptitration			

continued...

Trial	Treatments	Patients	Trials design and methods
CV181-040 [NCT00313313] n=NA follow-up: 24 weeks	saxagliptin added to a submaximal sulphonylurea dose versus uptitration of sulphonylurea monotherapy	patients with type 2 diabetes and inadequate glycaemic control with sulphonylurea monotherapy	
saxagliptin plus metformin XR 1500mg vs metformin up to 2000mg			
CV181-085 [NCT00918138] n=NA follow-up:	Saxagliptin in Combination With Metformin XR 1500 mg versus Up-titrated Metformin XR to 2000 mg	Subjects With Type 2 Diabetes Who Have Inadequate Glycemic Control With Diet and Exercise and a Stable Dose of Metformin XR 1500 mg	
saxagliptin vs placebo			
SAVOR TIMI , 2013 [NCT01107886] n=8280/8212 follow-up: 2.1 years (median)	saxagliptin versus placebo	patients with type 2 diabetes who had a history of, or were at risk for, cardiovascular events	Parallel groups double-blind
SAVOR-TIMI 53 , 2013 [NCT01107886] n=16500 follow-up:	Saxagliptin 5 mg or 2.5 mg once daily versus Placebo	Patients With Type 2 Diabetes	Parallel groups USA
saxagliptin vs placebo (add on current treatment)			
saxgliptin, renal study n=NA follow-up: 12 weeks	saxagliptin versus placebo added to patients current diabetes treatment	patients with moderate to severe renal impairment or end-stage renal disease	Parallel groups
saxagliptin vs placebo (add on insulin)			
CV181-057 [NCT00757588] n=NA follow-up:	Saxagliptin, 5 mg versus placebo (on top insulin)	Subjects With Type 2 Diabetes Who Have Inadequate Glycemic Control on Insulin Alone or on Insulin in Combination With Metformin	
saxagliptin vs placebo (add on MET)			
CV181-066 [NCT00683657] n=NA follow-up:	Saxagliptin versus placebo	Subjects With Type 2 Diabetes Who Have Inadequate Glycemic Control With Diet And Exercise And A Stable Dose Of Metformin 1500 mg/Day	
CV181-080 [NCT00885378] n=NA follow-up:	2.5 mg Saxagliptin, Twice Daily versus placebo	Subjects With Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control on Metformin IR Alone	

continued...

Trial	Treatments	Patients	Trials design and methods
DeFronzo , 2009 [NCT00121667] n=191/179 follow-up: 24 weeks	saxagliptin (2.5, 5, or 10 mg once daily) versus placebo	Patients With Inadequately Controlled Type 2 Diabetes With Metformin Alone	
Jadzinsky , 2009 [NCT00327015] n=NA follow-up:	saxagliptin versus placebo	treatment-naive patients with type 2 diabetes (T2D) and inadequate glycaemic control	
saxagliptin vs placebo (add on TZD)			
Hollander [NCT00295633] n=NA follow-up:	saxagliptin (2.5 or 5 mg) versus placebo	patients with type 2 diabetes and inadequate control on thiazolidinedione alone	
saxagliptin vs placebo (monotherapy)			
CV181-011 <i>unpublished</i> [NCT00121641] n=NA follow-up: 24 weeks	oral saxagliptin 2.5, 5, or 10 mg once daily versus placebo	-	
CV181-038 [NCT00316082] n=NA follow-up:	Saxagliptin monotherapy versus placebo	type 2 diabetic subjects who are not controlled with diet and exercise	
CV181-041 [NCT00374907] n=NA follow-up:	Saxagliptin versus placebo	Subjects With Type 2 Diabetes Who Are Not Controlled With Diet and Exercise	
Rosenstock , 2008 [NCT00950599] n=NA follow-up: 12 weeks	saxagliptin 2.5, 5, 10, 20 or 40 mg once daily versus placebo	drug-naive patients with T2DM and inadequate glycaemic control	
saxagliptin vs sitagliptin (add on MET)			
saxagliptin vs sitagliptin n=403/398 follow-up: 18 weeks	saxagliptin 5 mg once daily add on metformin versus sitagliptin 100 mg once daily add on metformin	adults with type 2 diabetes who did not attain adequate glycemic control on metformin therapy alone	Parallel groups
Saxagliptin/Dapagliflozin vs Glargine insulin			

continued...

Trial	Treatments	Patients	Trials design and methods
CV181-369 <i>ongoing</i> [NCT02551874] n=NA follow-up:	-	-	USA
saxagliptin vs glipizide			
saxagliptin n=NA follow-up: 52 weeks	saxagliptin versus titrated glipizide plus metformin	adult patients with type 2 diabetes and inadequate glycemc control	Parallel groups double-blind

More details and results :

- 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>
- 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>
- antidiabetic drugs for diabetes type 2 in patients inadequately controlled with insulin at <http://www.trialresultscenter.org/go-Q513>
- antidiabetic drugs for diabetes type 2 in in patients inadequately controlled on standard therapy at <http://www.trialresultscenter.org/go-Q544>
- antidiabetic drugs for diabetes type 2 in patients inadequately controlled on TZD at <http://www.trialresultscenter.org/go-Q545>
- antidiabetic drugs for diabetes type 2 in drug nave patients at <http://www.trialresultscenter.org/go-Q546>
- insulin secretagogues - DPP-4 inhibitors for diabetes type 2 in all types of patients at <http://www.trialresultscenter.org/go-Q550>
- glucose lowering for cardiovascular prevention for diabetes type 2 in all type of patients at <http://www.trialresultscenter.org/go-Q576>

References

Fonseca, 2012:

Fonseca V, Zhu T, Karyekar C, Hirshberg B Adding saxagliptin to extended-release metformin vs. uptitrating metformin dosage. Diabetes Obes Metab 2012;14:365-71 [22192246] [10.1111/j.1463-1326.2011.01553.x](https://doi.org/10.1111/j.1463-1326.2011.01553.x)

Forst, 2011:**Gke, 2010:**

Gke B, Gallwitz B, Eriksson J, Hellqvist A, Gause-Nilsson I Saxagliptin is non-inferior to glipizide in patients with type 2 diabetes mellitus inadequately controlled on metformin alone: a 52-week randomised controlled trial. *Int J Clin Pract* 2010;64:1619-31 [20846286] [10.1111/j.1742-1241.2010.02510.x](https://doi.org/10.1111/j.1742-1241.2010.02510.x)

Kawamori, 2012:

Kawamori R, Inagaki N, Araki E, Watada H, Hayashi N, Horie Y, Sarashina A, Gong Y, von Eynatten M, Woerle HJ, Dugi KA Linagliptin monotherapy provides superior glycaemic control versus placebo or voglibose with comparable safety in Japanese patients with type 2 diabetes: a randomized, placebo and active comparator-controlled, double-blind study. *Diabetes Obes Metab* 2012;14:348-57 [22145698] [10.1111/j.1463-1326.2011.01545.x](https://doi.org/10.1111/j.1463-1326.2011.01545.x)

Horie Y, Hayashi N, Dugi K, Takeuchi M Design, statistical analysis and sample size calculation of a phase IIb/III study of linagliptin versus voglibose and placebo. *Trials* 2009;10:82 [19732457] [10.1186/1745-6215-10-82](https://doi.org/10.1186/1745-6215-10-82)

Nowicki, 2011:

Nowicki M, Rychlik I, Haller H, Warren M, Suchower L, Gause-Nilsson I, Shtzer KM Long-term treatment with the dipeptidyl peptidase-4 inhibitor saxagliptin in patients with type 2 diabetes mellitus and renal impairment: a randomised controlled 52-week efficacy and safety study. *Int J Clin Pract* 2011;65:1230-9 [21977965] [10.1111/j.1742-1241.2011.02812.x](https://doi.org/10.1111/j.1742-1241.2011.02812.x)

Nowicki, 2011:

Nowicki M, Rychlik I, Haller H, Warren ML, Suchower L, Gause-Nilsson I Saxagliptin improves glycaemic control and is well tolerated in patients with type 2 diabetes mellitus and renal impairment. *Diabetes Obes Metab* 2011;13:523-32 [21332627] [10.1111/j.1463-1326.2011.01382.x](https://doi.org/10.1111/j.1463-1326.2011.01382.x)

Scheen , 2010:

Scheen AJ, Charpentier G, Ostgren CJ, Hellqvist A, Gause-Nilsson I Efficacy and safety of saxagliptin in combination with metformin compared with sitagliptin in combination with metformin in adult patients with type 2 diabetes mellitus. *Diabetes Metab Res Rev* 2010;26:540-9 [20824678] [10.1002/dmrr.1114](https://doi.org/10.1002/dmrr.1114)

Stenlf , 2010:

Stenlf K, Raz I, Neutel J, Ravichandran S, Berglind N, Chen R Saxagliptin and metformin XR combination therapy provides glycemic control over 24 hours in patients with T2DM inadequately controlled with metformin. *Curr Med Res Opin* 2010;26:2355-63 [20804445] [10.1185/03007995.2010.511090](https://doi.org/10.1185/03007995.2010.511090)

Yang, 2011:

Yang W, Pan CY, Tou C, Zhao J, Gause-Nilsson I Efficacy and safety of saxagliptin added to metformin in Asian people with type 2 diabetes mellitus: a randomized controlled trial. *Diabetes Res Clin Pract* 2011;94:217-24 [21871686] [10.1016/j.diabres.2011.07.035](https://doi.org/10.1016/j.diabres.2011.07.035)

CV181-040, :

Chacra AR, Tan GH, Apanovitch A, Ravichandran S, List J, Chen R Saxagliptin added to a submaximal dose of sulphonylurea improves glycaemic control compared with uptitration of sulphonylurea in patients with type 2 diabetes: a randomised controlled trial. *Int J Clin Pract* 2009 Sep;63:1395-406 [19614786]

Chacra AR, Tan GH, Ravichandran S, List J, Chen R Safety and efficacy of saxagliptin in combination with submaximal sulphonylurea versus up-titrated sulphonylurea over 76 weeks. *Diab Vasc Dis Res* 2011;8:150-9 [21562067] [10.1177/14791641111404574](https://doi.org/10.1177/14791641111404574)

CV181-085, :**SAVOR TIMI, 2013:**

Scirica BM, Bhatt DL, Braunwald E, Steg PG, Davidson J, Hirshberg B, Ohman P, Frederich R, Wiviott SD, Hoffman EB, Cavender MA, Udell JA, Desai NR, Mosenson O, McGuire DK, Ray KK, Leiter LA, Raz I Saxagliptin and cardiovascular outcomes in patients with type 2 diabetes mellitus. *N Engl J Med* 2013;369:1317-26 [23992601]

SAVOR-TIMI 53, 2013:

Scirica BM, Bhatt DL, Braunwald E, Steg PG, Davidson J, Hirshberg B, Ohman P, Price DL, Chen R, Udell J, Raz I The design and rationale of the saxagliptin assessment of vascular outcomes recorded in patients with diabetes mellitus-thrombolysis in myocardial infarction (SAVOR-TIMI) 53 study. *Am Heart J* 2011;162:818-825.e6 [22093196] [10.1016/j.ahj.2011.08.006](https://doi.org/10.1016/j.ahj.2011.08.006)

Scirica BM, Bhatt DL, Braunwald E, Steg PG, Davidson J, Hirshberg B, Ohman P, Frederich R, Wiviott SD, Hoffman EB, Cavender MA, Udell JA, Desai NR, Mozenon O, McGuire DK, Ray KK, Leiter LA, Raz I Saxagliptin and Cardiovascular Outcomes in Patients with Type 2 Diabetes Mellitus. *N Engl J Med* 2013 Sep 2;: [23992601] [10.1056/NEJMoa1307684](https://doi.org/10.1056/NEJMoa1307684)

saxgliptin, renal study, :**CV181-057, :****CV181-066, :****CV181-080, :****DeFronzo, 2009:**

DeFronzo RA, Hissa MN, Garber AJ, Luiz Gross J, Yuyan Duan R, Ravichandran S, Chen RS The efficacy and safety of saxagliptin when added to metformin therapy in patients with inadequately controlled type 2 diabetes with metformin alone. *Diabetes Care* 2009;32:1649-55 [19478198] [10.2337/dc08-1984](https://doi.org/10.2337/dc08-1984)

Karyekar C, Donovan M, Allen E, Fleming D, Ravichandran S, Chen R Efficacy and safety of saxagliptin combination therapy in US patients with type 2 diabetes. *Postgrad Med* 2011 Jul;123:63-70 [21680990]

Jadzinsky, 2009:

Jadzinsky M, Pftzner A, Paz-Pacheco E, Xu Z, Allen E, Chen R Saxagliptin given in combination with metformin as initial therapy improves glycaemic control in patients with type 2 diabetes compared with either monotherapy: a randomized controlled trial. *Diabetes Obes Metab* 2009 Jun;11:611-22 [19515181]

Pftzner A, Paz-Pacheco E, Allen E, Frederich R, Chen R Initial combination therapy with saxagliptin and metformin provides sustained glycaemic control and is well tolerated for up to 76 weeks. *Diabetes Obes Metab* 2011;13:567-76 [21342412] [10.1111/j.1463-1326.2011.01385.x](https://doi.org/10.1111/j.1463-1326.2011.01385.x)

Hollander, :

Hollander P, Li J, Allen E, Chen R Saxagliptin added to a thiazolidinedione improves glycemic control in patients with type 2 diabetes and inadequate control on thiazolidinedione alone. *J Clin Endocrinol Metab* 2009 Dec;94:4810-9 [19864452]

Hollander PL, Li J, Frederich R, Allen E, Chen R Safety and efficacy of saxagliptin added to thiazolidinedione over 76 weeks in patients with type 2 diabetes mellitus. *Diab Vasc Dis Res* 2011;8:125-35 [21562064] [10.1177/1479164111404575](https://doi.org/10.1177/1479164111404575)

CV181-011, :

unpublished

Rosenstock J, Aguilar-Salinas C, Klein E, Nepal S, List J, Chen R Effect of saxagliptin monotherapy in treatment-naive patients with type 2 diabetes. *Curr Med Res Opin* 2009;25:2401-11 [19650754] [10.1185/03007990903178735](https://doi.org/10.1185/03007990903178735)

CV181-038, :**CV181-041, :****Rosenstock, 2008:**

Rosenstock J, Sankoh S, List JF Glucose-lowering activity of the dipeptidyl peptidase-4 inhibitor saxagliptin in drug-naive patients with type 2 diabetes. *Diabetes Obes Metab* 2008 May;10:376-86 [18355324]

saxagliptin vs sitagliptin, :

CV181-369, 0:

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