

Clinical trials of linagliptin

TrialResults-center www.trialresultscenter.org

1 diabetes type 2

Trial	Treatments	Patients	Trials design and methods
linagliptin vs			
Forst , 2010 [NCT00309608] n=NA follow-up: 12 weeks	Linagliptin (1, 5, or 10 mg taken once daily) versus placebo (on top Metformin)	patients with type 2 diabetes mellitus who are not at goal with their HbA1c levels	double-blind France
linagliptin vs glimepiride			
CAROLINA , 2012 [NCT01243424] n=776/775 follow-up: 2 years	linagliptin versus glimepiride 1-4 mg QD	patients with type 2 diabetes at elevated cardiovascular risk receiving usual care	double-blind USA
linagliptin vs glimepiride (add on MET)			
Gallwitz , 2012 [NCT00622284] n=777/775 follow-up: 104 weeks	linagliptin (5 mg once daily) add-on therapy to preferably >1500 mg metformin versus glimepiride (14 mg) orally once daily add-on therapy to preferably >1500 mg metformin	type 2 diabetes mellitus with insufficient glycaemic control with metformin	Parallel groups double-blind USA
linagliptin vs Metformin + sulfonylurea			
Owens [NCT00602472] n=NA follow-up: 24 weeks	linagliptin versus combination of metformin and an SU	type 2 diabetes mellitus with insufficient glycaemic control with metformin in combination with a sulphonylurea	Argentina
linagliptin vs placebo			
Del Prato [NCT00621140] n=NA follow-up: 24 weeks	Linagliptin monotherapy versus placebo	Type 2 Diabetic Patients With Insufficient Glycemic Control	double-blind Croatia

continued...

Trial	Treatments	Patients	Trials design and methods
CARMELINA <i>ongoing</i> [NCT01897532] n=NA follow-up:	-	-	double-blind
linagliptin 1218.46 <i>ongoing</i> [NCT00798161] n=NA follow-up: 24 weeks	-	drug naive or previously treated type 2 diabetic patients with insufficient glycaemic control	Canada
linagliptin1218.5 <i>ongoing</i> [NCT00328172] n=NA follow-up: 12 weeks	linagliptin (0.5, 2.5 and 5 mg daily) versus placebo	patients with Type 2 diabetes and insufficient glycaemic control	
linagliptine 1218.50 <i>ongoing</i> [NCT00740051] n=NA follow-up: 18 weeks	Linagliptin versus Placebo	patients for whom metformin therapy is inappropriate (intolerability, contraindication)	double-blind USA
linagliptin vs placebo (add on MET)			
Taskinen [NCT00601250] n=524/177 follow-up:	linagliptin 5 mg once daily versus placebo add on MET	patients with inadequately controlled type 2 diabetes for whom metformin therapy is inappropriate due to intolerability or contraindication	
linagliptin 1218.65 <i>ongoing</i> [NCT01215097] n=NA follow-up: 24 weeks	5 mg of Linagliptin administered orally once daily versus placebo (on top metformin)	patients with type 2 diabetes and insufficient glycaemic control with metformin	parallel groups double-blind China
linagliptin vs placebo (add on pioglitazone)			
Gomis , 2011 [NCT00641043] n=NA follow-up: 24 weeks	initial combination of 30 mg pioglitazone plus 5 mg linagliptin versus pioglitazone plus placebo	patients with inadequately controlled type 2 diabetes	
linagliptin vs placebo (add on SU)			
Lewin , 2010 [NCT00819091] n=NA follow-up: 18 weeks	linagliptin 5 mg versus placebo (add-on to sulphonylurea)	patients with type 2 diabetes and insufficient glycaemic control	double-blind
linagliptin low dose vs linagliptin			

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Trial	Treatments	Patients	Trials design and methods
linagliptin 1218.62 <i>ongoing</i> [NCT01012037] n=NA follow-up: 12 weeks	linagliptin low dose 2.5 mg twice daily versus linagliptin medium dose 5 mg once daily	patients with type 2 diabetes mellitus with insufficient glycaemic control with metformin	double-blind Belgium
linagliptin vs placebo (add on MET+TZD)			
linagliptin 1218.61 <i>ongoing</i> [NCT00996658] n=NA follow-up:	Linagliptin (5 mg once daily) versus placebo (add on therapy to metformin in combination with pioglitazone)	Type 2 Diabetic Patients With Inadequate Glycaemic Control on Metformin in Combination With Pioglitazone	
linagliptin + pioglitazone vs pioglitazone			
linagliptin 1264.3 <i>ongoing</i> [NCT01183013] n=NA follow-up: 30 weeks	linagliptin/pioglitazone (5/15, 5/30 and 5/45 mg) linagliptine versus pioglitazone	-	

More details and results :

- insulin secretagogues for diabetes type 2 in all type of patients at <http://www.trialresultscenter.org/go-Q409>
- 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 MET+SU therapy at <http://www.trialresultscenter.org/go-Q510>
- antidiabetic drugs for diabetes type 2 in patients with insufficient glycaemic control with bitherapy at <http://www.trialresultscenter.org/go-Q511>
- 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 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>
- antidiabetic drugs for diabetes type 2 in patients insufficiently controlled on SU at <http://www.trialresultscenter.org/go-Q547>
- 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

Forst, 2010:

Forst T, Uhlig-Laske B, Ring A, Graefe-Mody U, Friedrich C, Herbach K, Woerle HJ, Dugi KA Linagliptin (BI 1356), a potent and selective DPP-4 inhibitor, is safe and efficacious in combination with metformin in patients with inadequately controlled Type 2 diabetes. *Diabet Med* 2010;27:1409-19 [21059094] [10.1111/j.1464-5491.2010.03131.x](#)

CAROLINA, 2012:

Gallwitz B, Rosenstock J, Rauch T, Bhattacharya S, Patel S, von Eynatten M, Dugi KA, Woerle HJ 2-year efficacy and safety of linagliptin compared with glimepiride in patients with type 2 diabetes inadequately controlled on metformin: a randomised, double-blind, non-inferiority trial. *Lancet* 2012 Aug 4;380:475-83 [22748821] [10.1016/S0140-6736\(12\)60691-6](#)

Gallwitz, 2012:

Gallwitz B, Rosenstock J, Rauch T, Bhattacharya S, Patel S, von Eynatten M, Dugi KA, Woerle HJ 2-year efficacy and safety of linagliptin compared with glimepiride in patients with type 2 diabetes inadequately controlled on metformin: a randomised, double-blind, non-inferiority trial. *Lancet* 2012 Aug 4;380:475-83 [22748821] [10.1016/S0140-6736\(12\)60691-6](#)

Owens, 0:

Owens DR, Swallow R, Woerle HJ, et al. Linagliptin improves glycemic control in Type 2 diabetes patients inadequately controlled by metformin and sulfonylurea without weight gain and low risk of hypoglycaemia. Poster no 548-P, 70th American Diabetes Association Scientific Sessions, June 2010, Orlando, Florida U.S.A.

Owens DR, Swallow R, Dugi KA, Woerle HJ Efficacy and safety of linagliptin in persons with type 2 diabetes inadequately controlled by a combination of metformin and sulphonylurea: a 24-week randomized study. *Diabet Med* 2011;28:1352-61 [21781152] [10.1111/j.1464-5491.2011.03387.x](#)

Del Prato, 0:

Del Prato S, Barnett A, Huisman H, et al. Linagliptin monotherapy improves glycaemic control and measures of beta-cell function in Type 2 diabetes. Poster no 695-P, 70th American Diabetes Association Scientific Sessions, June 2010, Orlando, Florida, U.S.A

Del Prato S, Barnett AH, Huisman H, Neubacher D, Woerle HJ, Dugi KA Effect of linagliptin monotherapy on glycaemic control and markers of β -cell function in patients with inadequately controlled type 2 diabetes: a randomized controlled trial. *Diabetes Obes Metab* 2011;13:258-67 [21205122] [10.1111/j.1463-1326.2010.01350.x](#)

CARMELINA, :

ongoing trial NCT01897532

linagliptin 1218.46, 0:

ongoing trial NCT00798161

linagliptin1218.5, 0:

ongoing trial NCT00328172

linagliptine 1218.50, 0:

ongoing trial NCT00740051

Taskinen, 0:

IBarnett AH, Harper R, Toorawa R, et al. Linagliptin monotherapy improves glycaemic control in type 2 diabetes patients for whom metformin therapy is inappropriate. Poster no. 823-P, 46th European Association for the Study of Diabetes Annual Meeting, September 2010, Stockholm, Sweden.

Taskinen MR, Rosenstock J, Tamminen I, Kubiak R, Patel S, Dugi KA, Woerle HJ Safety and efficacy of linagliptin as add-on therapy to metformin in patients with type 2 diabetes: a randomized, double-blind, placebo-controlled study. *Diabetes Obes Metab* 2011;13:65-74 [21114605] [10.1111/j.1463-1326.2010.01326.x](#)

linagliptin 1218.65, 0:

ongoing trial NCT01215097

Gomis, 2011:

Gomis R, Espadero RM, Jones R, Woerle HJ, Dugi KA Efficacy and safety of initial combination therapy with linagliptin and pioglitazone in patients with inadequately controlled type 2 diabetes: a randomized, double-blind, placebo-controlled study. *Diabetes Obes Metab* 2011;13:653-61 [21410628] [10.1111/j.1463-1326.2011.01391.x](https://doi.org/10.1111/j.1463-1326.2011.01391.x)

Lewin, 2010:

Lewin AJ, Arvay L, Liu D, et al. Safety and efficacy of linagliptin as add-on therapy to a sulphonylurea in inadequately controlled type 2 diabetes. Poster no. 821-P, 46th European Association for the Study of Diabetes Annual Meeting, September 2010, Stockholm, Sweden

linagliptin 1218.62, 0:

ongoing trial NCT01012037

linagliptin 1218.61, 0:

ongoing trial NCT00996658

linagliptin 1264.3, 0:

ongoing trial NCT01183013

Entry terms: pioglitazone, Actos, Linagliptin, Tradjenta, BI 1356, BI1356, BI-1356,