

Clinical trials of liraglutide 1.8mg

TrialResults-center www.trialresultscenter.org

1 diabetes type 2

Trial	Treatments	Patients	Trials design and methods
liraglutide 1.8mg vs placebo (add on MET)			
LEAD-2 (Nauck) (1.8mg vs placebo) , 2009 [NCT00318461] n=242/122 follow-up: 26 weeks	Liraglutide 1.8 mg daily versus Placebo on-top of Metformin	subjects previously treated with oral antidiabetes therapy	Parallel groups double blind 21 countries
liraglutide 1.8mg vs placebo (add on SU)			
LEAD-1 SU (1.8 mg vs placebo) , 2009 [NCT00318422] n=234/114 follow-up: 26 weeks	Liraglutide 1.8 mg daily versus Placebo on-top of sulphonylureas	patients with type 2 diabetes	Parallel groups double-blind 21 countries
liraglutide 1.8mg vs placebo (add on SU+MET)			
LEAD-5 (vs placebo) , 2009 [NCT00331851] n=232/115 follow-up: 26 weeks	Liraglutide 1.8 mg daily versus Placebo on-top of sulphonylureas+metformin	adult patients with type 2 diabetes	Parallel groups double-blind 17 countries
liraglutide 1.8mg vs placebo (add on TZD+MET)			
LEAD-4 (1.8mg) , 2009 [NCT00333151] n=178/177 follow-up: 26 weeks	Liraglutide 1.8 daily versus Placebo on-top of thiazolidinediones + metformin	patients with type 2 diabetes, A1C 711% (previous OAD monotherapy >=3 months) or 710% (previous OAD combination therapy >=3 months), and BMI 45 kg/m2	double-blind USA, Canada
liraglutide 1.8mg vs exenatide on top MET/SU/MET+SU			
LEAD-6 , 2009 [NCT00518882] n=233/231 follow-up: 26 weeks	liraglutide 1.8 mg once a day versus exenatide 10 microg twice a day	Adults with inadequately controlled type 2 diabetes on maximally tolerated doses of metformin, sulphonylurea, or both	Parallel groups open 15 countries
liraglutide 1.8mg vs glimepiride			

continued...

Trial	Treatments	Patients	Trials design and methods
LEAD-3 mono 1.8mg (Garber) , 2009 [NCT00294723] n=247/248 follow-up: 52 weeks (104 weeks)	liraglutide 1.8 mg daily versus glimepiride 8 mg once daily	subjects with type 2 diabetes	Parallel groups double blind North America, Mexico
liraglutide 1.8mg vs glimepiride (add on MET)			
LEAD-2 (Nauck) (1.8 mg vs glimepiride) , 2009 [NCT00318461] n=242/244 follow-up: 26 weeks	Liraglutide 1.8 mg daily for 26 weeks versus Glimepiride on-top of Metformin	patients with type 3 diabetes previously treated with oral antidiabetes (OAD) therap	Parallel groups double blind 21 countries
liraglutide 1.8mg vs insulin glargine (add on SU+MET)			
LEAD-5 (vs Glargine) , 2009 [NCT00331851] n=232/234 follow-up: 26 weeks	Liraglutide 1.8 mg daily versus Glargine on-top of sulphonylureas+metformin	adult patients with type 2 diabetes	Parallel groups open 17 countries
liraglutide 1.8mg vs liraglutide 1.2mg			
LEAD 1 (1.8 vs 1.2) , 2009 n=NA	-	-	
LEAD 2 (1.8 vs 1.2) , 2009 n=NA	-	-	
LEAD 4 (1.8 vs 1.2) , 2009 n=NA	-	-	
Pratley (1.8 vs 1.2) , 2010 n=NA	-	-	
liraglutide 1.8mg vs sitagliptin			
Pratley 1.8mg , 2010 [NCT00700817] n=221/219 follow-up: 26 weeks	liraglutide 1.8mg subcutaneously once daily versus oral sitagliptin 100mg once daily	patients with type 2 diabetes who did not have adequate glycemic control with metformin	Parallel groups open Europe, USA, Canada

More details and results :

- insulin secretagogues peptides (incretins) for diabetes type 2 in all type of patients at <http://www.trialresultscenter.org/go-Q381>
- 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>

References

LEAD-2 (Nauck) (1.8mg vs placebo), 2009:

Nauck M, Frid A, Hermansen K, Shah NS, Tankova T, Mitha IH, Zdravkovic M, Dring M, Matthews DR Efficacy and safety comparison of liraglutide, glimepiride, and placebo, all in combination with metformin, in type 2 diabetes: the LEAD (liraglutide effect and action in diabetes)-2 study. *Diabetes Care* 2009;32:84-90 [[18931095](#)] [10.2337/dc08-1355](#)

LEAD-1 SU (1.8 mg vs placebo), 2009:

Marre M, Shaw J, Brndle M, Bebakar WM, Kamaruddin NA, Strand J, Zdravkovic M, Le Thi TD, Colagiuri S Liraglutide, a once-daily human GLP-1 analogue, added to a sulphonylurea over 26 weeks produces greater improvements in glycaemic and weight control compared with adding rosiglitazone or placebo in subjects with Type 2 diabetes (LEAD-1 SU). *Diabet Med* 2009;26:268-78 [[19317822](#)] [10.1111/j.1464-5491.2009.02666.x](#)

LEAD-5 (vs placebo), 2009:

Russell-Jones D, Vaag A, Schmitz O, Sethi BK, Lalic N, Antic S, Zdravkovic M, Ravn GM, Sim R Liraglutide vs insulin glargine and placebo in combination with metformin and sulphonylurea therapy in type 2 diabetes mellitus (LEAD-5 met+SU): a randomised controlled trial. *Diabetologia* 2009;52:2046-55 [[19688338](#)] [10.1007/s00125-009-1472-y](#)

LEAD-4 (1.8mg), 2009:

Zinman B, Gerich J, Buse JB, Lewin A, Schwartz S, Raskin P, Hale PM, Zdravkovic M, Blonde L, , Efficacy and safety of the human glucagon-like peptide-1 analog liraglutide in combination with metformin and thiazolidinedione in patients with type 2 diabetes (LEAD-4 Met+TZD). *Diabetes Care* 2009;32:1224-30. [[19289857](#)] [10.2337/dc08-2124](#)

LEAD-6, 2009:

Buse JB, Rosenstock J, Sesti G, Schmidt WE, Montanya E, Brett JH, Zychma M, Blonde L Liraglutide once a day versus exenatide twice a day for type 2 diabetes: a 26-week randomised, parallel-group, multinational, open-label trial (LEAD-6). *Lancet* 2009 Jul 4;374:39-47 [[19515413](#)] [10.1016/S0140-6736\(09\)60659-0](#)

Buse JB, Sesti G, Schmidt WE, Montanya E, Chang CT, Xu Y, Blonde L, Rosenstock J Switching to once-daily liraglutide from twice-daily exenatide further improves glycemic control in patients with type 2 diabetes using oral agents. *Diabetes Care* 2010;33:1300-3 [[20332351](#)] [10.2337/dc09-2260](#)

Schmidt WE, Christiansen JS, Hammer M, Zychma MJ, Buse JB Patient-reported outcomes are superior in patients with Type?2 diabetes treated with liraglutide as compared with exenatide, when added to metformin, sulphonylurea or both: results from a randomized, open-label study. *Diabet Med* 2011 Mar 9;: [[21388442](#)] [10.1111/j.1464-5491.2011.03276.x](#)

LEAD-3 mono 1.8mg (Garber), 2009:

Garber A, Henry R, Ratner R, Garcia-Hernandez PA, Rodriguez-Pattzi H, Olvera-Alvarez I, Hale PM, Zdravkovic M, Bode B Liraglutide versus glimepiride monotherapy for type 2 diabetes (LEAD-3 Mono): a randomised, 52-week, phase III, double-blind, parallel-treatment trial. *Lancet* 2009;373:473-81 [[18819705](#)] [10.1016/S0140-6736\(08\)61246-5](#)

LEAD-2 (Nauck) (1.8 mg vs glimepiride), 2009:

Nauck M, Frid A, Hermansen K, Shah NS, Tankova T, Mitha IH, Zdravkovic M, Dring M, Matthews DR Efficacy and safety comparison of liraglutide, glimepiride, and placebo, all in combination with metformin, in type 2 diabetes: the LEAD (liraglutide effect and action in diabetes)-2 study. *Diabetes Care* 2009;32:84-90 [[18931095](#)] [10.2337/dc08-1355](#)

LEAD-5 (vs Glargine), 2009:

Russell-Jones D, Vaag A, Schmitz O, Sethi BK, Lalic N, Antic S, Zdravkovic M, Ravn GM, Sim R Liraglutide vs insulin glargine and placebo in combination with metformin and sulfonylurea therapy in type 2 diabetes mellitus (LEAD-5 met+SU): a randomised controlled trial. *Diabetologia* 2009 Oct;52:2046-55 [[19688338](#)]

Sullivan SD, Alfonso-Cristancho R, Conner C, Hammer M, Blonde L Long-term outcomes in patients with type 2 diabetes receiving glimepiride combined with liraglutide or rosiglitazone. *Cardiovasc Diabetol* 2009 Feb 26;8:12 [[19245711](#)]

LEAD 1 (1.8 vs 1.2), 2009:

LEAD 2 (1.8 vs 1.2), 2009:

LEAD 4 (1.8 vs 1.2), 2009:

Pratley (1.8 vs 1.2), 2010:

Pratley 1.8mg, 2010:

Pratley RE, Nauck M, Bailey T, Montanya E, Cuddihy R, Filetti S, Thomsen AB, Sndergaard RE, Davies M Liraglutide versus sitagliptin for patients with type 2 diabetes who did not have adequate glycaemic control with metformin: a 26-week, randomised, parallel-group, open-label trial. *Lancet* 2010 Apr 24;375:1447-1456 [[20417856](#)] [10.1016/S0140-6736\(10\)60307-8](#)

Entry terms: liraglutide, liraglutide, victoza