

Clinical trials of liraglutide 1.2mg

TrialResults-center www.trialresultscenter.org

1 diabetes type 2

Trial	Treatments	Patients	Trials design and methods
liraglutide 1.2mg vs placebo (add on MET)			
LEAD-2 (Nauck) (1.2mg vs placebo) , 2009 [NCT00318461] n=241/122 follow-up: 26 weeks	Liraglutide 1.2 mg daily versus Placebo on-top of Metformin	subjects previously treated with oral antidiabetes therapy	Parallel groups double blind 21 countries
liraglutide 1.2mg vs placebo (add on SU)			
LEAD-1 SU (1.2 mg vs placebo) , 2009 [NCT00318422] n=228/115 follow-up: 26 weeks	Liraglutide 1.2 mg daily versus Placebo on-top of sulphonylureas	subjects with Type 2 diabetes	Parallel groups double-blind 21 countries
liraglutide 1.2mg vs placebo (add on TZD+MET)			
LEAD-4 (1.2mg) , 2009 [NCT00333151] n=178/177 follow-up: 26 weeks	Liraglutide 1.2 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	Parallel groups double-blind USA, Canada
liraglutide 1.2mg vs glimepiride			
LEAD-3 mono 1.2mg (Garber) , 2009 [NCT00294723] n=251/248 follow-up: 52 weeks (104 weeks)	liraglutide 1.2 mg daily versus glimepiride 8 mg once daily	patients with early type 2 diabetes	Parallel groups double blind North America, Mexico
liraglutide 1.2mg vs glimepiride (add on MET)			
LEAD-2 (Nauck) (1.2 mg vs glimepiride) , 2009 [NCT00318461] n=241/244 follow-up: 26 weeks	Liraglutide 1.2mg 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 1.2mg vs rosiglitazone			

continued...

Trial	Treatments	Patients	Trials design and methods
LEAD-1 SU (1.2 vs rosiglitazone) , 2009 n=NA	-	-	
liraglutide 1.2mg vs sitagliptin			
Pratley 1.2mg , 2010 [NCT00700817] n=225/219 follow-up: 26 weeks	liraglutide 1.2mg 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 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) (1.2mg 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

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;8:12 [19245711] 10.1186/1475-2840-8-12

Nauck M, Marre M Adding liraglutide to oral antidiabetic drug monotherapy: efficacy and weight benefits. *Postgrad Med* 2009;121:5-15 [19491535] 10.3810/pgm.2009.05.1997

LEAD-1 SU (1.2 mg vs placebo), 2009:

Nauck M, Marre M Adding liraglutide to oral antidiabetic drug monotherapy: efficacy and weight benefits. *Postgrad Med* 2009;121:5-15 [19491535] 10.3810/pgm.2009.05.1997

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

Gallwitz B, Vaag A, Falahati A, Madsbad S Adding liraglutide to oral antidiabetic drug therapy: onset of treatment effects over time. *Int J Clin Pract* 2010;64:267-76 [19925617] 10.1111/j.1742-1241.2009.02265.x

LEAD-4 (1.2mg), 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-3 mono 1.2mg (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](#)

Bode BW, Testa MA, Magwire M, Hale PM, Hammer M, Blonde L, Garber A, , Patient-reported outcomes following treatment with the human GLP-1 analogue liraglutide or glimepiride in monotherapy: results from a randomized controlled trial in patients with type 2 diabetes. *Diabetes Obes Metab* 2010;12:604-12. [[20590735](#)] [10.1111/j.1463-1326.2010.01196.x](#)

Garber A, Henry RR, Ratner R, Hale P, Chang CT, Bode B Liraglutide, a once-daily human glucagon-like peptide 1 analogue, provides sustained improvements in glycaemic control and weight for 2 years as monotherapy compared with glimepiride in patients with type 2 diabetes. *Diabetes Obes Metab* 2011;13:348-56 [[21205128](#)] [10.1111/j.1463-1326.2010.01356.x](#)

LEAD-2 (Nauck) (1.2 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](#)

Hermansen K, Kolotkin RL, Hammer M, Zdravkovic M, Matthews D, Patient-reported outcomes in patients with type 2 diabetes treated with liraglutide or glimepiride, both as add-on to metformin. *Prim Care Diabetes* 2010;4:113-7. [[20444662](#)] [10.1016/j.pcd.2010.04.001](#)

Diabetologia 52 (2009) S8.

LEAD-1 SU (1.2 vs rosiglitazone), 2009:**Pratley 1.2mg, 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](#)

Pratley R, Nauck M, Bailey T, Montanya E, Cuddihy R, Filetti S, Garber A, Thomsen AB, Hartvig H, Davies M One year of liraglutide treatment offers sustained and more effective glycaemic control and weight reduction compared with sitagliptin, both in combination with metformin, in patients with type 2 diabetes: a randomised, parallel-group, open-label trial. *Int J Clin Pract* 2011;65:397-407 [[21355967](#)] [10.1111/j.1742-1241.2011.02656.x](#)

Entry terms: liraglutide, liraglutide, victoza