

# Clinical trials of liraglutide

TrialResults-center [www.trialresultscenter.org](http://www.trialresultscenter.org)

## 1 obesity and overweight

Trial	Treatments	Patients	Trials design and methods
<b>liraglutide vs placebo</b>			
<a href="#">Astrup (NN8022-1807)</a> , <a href="#">2009</a> [NCT00422058] n=NA follow-up: 20 weeks	4 liraglutide doses (1.2 mg, 1.8 mg, 2.4 mg, or 3.0 mg daily) versus placebo	obese individuals without type 2 diabetes	Parallel groups double blind Europe

More details and results :

- All mechanism for obesity and overweight in all type of patients at <http://www.trialresultscenter.org/go-Q265>

## References

**Astrup (NN8022-1807)** , **2009:**

Astrup A, Rssner S, Van Gaal L, Rissanen A, Niskanen L, Al Hakim M, Madsen J, Rasmussen MF, Lean ME Effects of liraglutide in the treatment of obesity: a randomised, double-blind, placebo-controlled study. Lancet 2009 Oct 22; [19853906] [10.1016/S0140-6736\(09\)61375-1](https://doi.org/10.1016/S0140-6736(09)61375-1)

## 2 diabetes type 2

Trial	Treatments	Patients	Trials design and methods
<b>liraglutide other doses vs</b>			
<a href="#">NN2211-1333</a> n=NA follow-up:	liraglutide versus placebo	obese subjects with type 2 diabetes	
<b>liraglutide vs placebo</b>			
<a href="#">LEADER</a> , <a href="#">2016</a> [NCT01179048] n=4668/4672 follow-up: 3.8 years (median)	Maximum dose of 1.8 mg liraglutide, injected subcutaneously once daily versus placebo	subjects with type 2 diabetes	double-blind Africa, Asia, Europe, North and South America

continued...

Trial	Treatments	Patients	Trials design and methods
<b>liraglutide other doses vs placebo</b>			
<b>Harder , 2004</b> n=21/12 follow-up: 8 weeks	single daily subcutaneous dose of 0.6 mg liraglutide for 8 weeks versus placebo	obese subjects with type 2 diabetes	Parallel groups double-blind Denmark
<b>Kaku 0.6mg , 2010</b> n=88/88 follow-up: 24 weeks	liraglutide 0.6 mg/day versus placebo	Japanese patients with type 2 diabetes	Parallel groups double-blind Japan
<b>Madsbad (vs placebo) , 2004</b> n=135/29 follow-up: 12 weeks	Liraglutide 0.045, 0.225, 0.45, 0.60, and 0.75 mg daily versus Placebo	Outpatients with type 2 diabetes	open UK, Scandinavia
<b>NN2211-1571 (Vilsbll) , 2007</b> [NCT00154401] n=123/40 follow-up: 14 weeks	liraglutide 0.65 mg, 1.25 mg or 1.9 mg for 14 weeks versus placebo	subjects with type 2 diabetes	Parallel groups double-blind Denmark, France, Slovakia, Netherlands
<b>Seino , 2008</b> [NCT00154414] n=180/46 follow-up: 14 weeks	Liraglutide 0.1, 0.3, 0.6 or 0.9 mg once daily for 14 weeks versus Placebo	Japanese subjects with type 2 diabetes	Parallel groups double blind Japan
<b>LIBRA ongoing</b> [NCT01270789] n=NA follow-up: 1 year	-	patients with T2DM	double-blind Canada
<b>NCT00978393 ongoing</b> [NCT00978393] n=NA follow-up:	High dose liraglutide treatment (3.0 mg) followed by low dose liraglutide treatment (1.8 mg) s.c. once daily versus placebo	non-diabetic obese volunteers	double-blind Netherlands
<b>NN2211-1799 ongoing</b> [NCT00620282] n=NA follow-up: 3 months	liraglutide Stepwise dose increase, s.c. injection, once daily versus placebo	subjects with type 2 diabetes who are on diet and lifestyle changes or treated with metformin alon	double-blind USA

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>NN2211-1800</b> <i>ongoing</i> [NCT00943501] n=NA follow-up:	-	children with type 2 diabetes	double-blind USA, Europe
<b>NN2211-3619</b> <i>ongoing</i> [NCT01206101] n=NA follow-up:	-	Type 1 Diabetes Undergoing Islet Cell Transplantation	
<b>NN8022-1922</b> <i>ongoing</i> [NCT01272232] n=NA follow-up: 56 weeks	Liraglutide 3.0 mg for subcutaneous (under the skin) injection once daily for 56 weeks in addition to subject's pre-trial background treatment versus placebo	overweight or obese subjects with type 2 diabetes	double-blind Africa, Asia, Europe and the United States of America
<b>NN8022-1923</b> <i>ongoing</i> [NCT00781937] n=NA follow-up: 56 weeks	Liraglutide 3.0 mg per day administered in a 6.0 mg/mL, 3 mL FlexPen for subcutaneous (s.c.) injection, once daily versus placebo	obese non-diabetic subjects or overweight subjects who have medical problems such as hypertension or dyslipidaemia	double-blind North America
<b>liraglutide 1.2mg vs placebo (add on MET)</b>			
<b>LEAD-2 (Nauck) (1.2mg vs placebo)</b> , 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
<b>liraglutide 1.8mg vs placebo (add on MET)</b>			
<b>LEAD-2 (Nauck) (1.8mg vs placebo)</b> , 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
<b>liraglutide other doses vs placebo (add on MET)</b>			
<b>NN2211-1796</b> <i>unpublished</i> [NCT00614120] n=NA follow-up:	liraglutide added to metformin versus glimepiride added to metformin	-	China
<b>NCT01234649</b> <i>ongoing</i> [NCT01234649] n=NA follow-up:	addition of liraglutide to metformin versus metformin alone	at-risk overweight/obese women with prior gestational diabetes mellitus	double-blind USA

continued...

Trial	Treatments	Patients	Trials design and methods
<b>liraglutide 1.2mg vs placebo (add on SU)</b>			
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
<b>liraglutide 1.8mg vs placebo (add on SU)</b>			
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
<b>liraglutide 1.8mg vs placebo (add on SU+MET)</b>			
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
<b>liraglutide 1.2mg vs placebo (add on TZD+MET)</b>			
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
<b>liraglutide 1.8mg vs placebo (add on TZD+MET)</b>			
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
<b>liraglutide other doses vs placebo (on top SU)</b>			
Kaku 0.9mg , 2010 n=88/88 follow-up: 24 weeks	liraglutide 0.9 mg/day versus placebo	Japanese patients with type 2 diabetes	double-blind Japan
<b>liraglutide other doses vs placebo (add on SU)</b>			

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>NN2211-1701</b> <i>ongoing</i> [NCT00395746] n=NA follow-up: 24 weeks	liraglutide in combination with sulphonylurea versus placebo (add on to SU monotherapy)	subjects with type 2 diabetes	Parallel groups double-blind Japan
<b>liraglutide other doses vs sitagliptin (add on MET)</b>			
<b>MK-0431-403</b> <i>ongoing</i> [NCT01296412] n=NA follow-up:	Liraglutide + metformin versus Sitagliptin + metformin	patients with Type 2 Diabetes that is not adequately controlled with metformin alone	parallel groups open
<b>liraglutide 1.8mg vs exenatide on top MET/SU/MET+SU</b>			
<b>LEAD-6 , 2009</b> [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
<b>liraglutide other doses vs glibenclamide</b>			
<b>Seino , 2010</b> [NCT00393718] n=272/139 follow-up: 24-week	liraglutide 0.9 mg once daily versus glibenclamide once or twice daily at a planned maximum dose of 2.5 mg/day, before or after meals	Japanese subjects with type 2 diabetes, inadequately controlled with diet therapy or oral antidiabetic drug monotherapy	Parallel groups double-blind Japan
<b>liraglutide 1.2mg vs glimepiride</b>			
<b>LEAD-3 mono 1.2mg (Garber) , 2009</b> [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
<b>liraglutide 1.8mg vs glimepiride</b>			
<b>LEAD-3 mono 1.8mg (Garber) , 2009</b> [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
<b>liraglutide other doses vs glimepiride</b>			
<b>Madsbad (vs Glimepiride) , 2004</b> n=135/26 follow-up: 12 weeks	Liraglutide 0.045, 0.225, 0.45, 0.60, and 0.75 mg daily versus Glimepiride	Outpatients with type 2 diabetes	Parallel groups open UK, Scandinavia

continued...

Trial	Treatments	Patients	Trials design and methods
<b>liraglutide 1.2mg vs glimepiride (add on MET)</b>			
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
<b>liraglutide 1.8mg vs glimepiride (add on MET)</b>			
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
<b>liraglutide 1.8mg vs insulin glargine (add on SU+MET)</b>			
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
<b>liraglutide 1.8mg vs liraglutide 1.2mg</b>			
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	-	-	
<b>liraglutide other doses vs metformin</b>			
Feinglos , 2005 n=176/34 follow-up: 12 weeks	Liraglutide 0.045, 0.225, 0.45, 0.6 or 0.75 mg daily for 12 weeks versus metformin 1000mg twice daily	subjects with Type 2 diabetes	Parallel groups double blind (not adequate)
<b>liraglutide 1.2mg vs rosiglitazone</b>			
LEAD-1 SU (1.2 vs rosiglitazone) , 2009 n=NA	-	-	
<b>liraglutide other doses vs rosiglitazone (add on SU)</b>			

continued...

Trial	Treatments	Patients	Trials design and methods
<b>LEAD-1 SU (1.8 vs rosiglitazone) , 2009</b> [NCT00318422] n=228/232 follow-up: 26 weeks	Liraglutide 0.6, 1.2 or 1.8 mg daily versus rosiglitazone on-top of sulphonylureas		Parallel groups double-blind 21 countries
<b>liraglutide 1.2mg vs sitagliptin</b>			
<b>Pratley 1.2mg , 2010</b> [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
<b>liraglutide 1.8mg vs sitagliptin</b>			
<b>Pratley 1.8mg , 2010</b> [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
<b>liraglutide other doses vs insulin glargine</b>			
<b>EAGLE ongoing</b> [NCT01117350] n=NA follow-up:	Liraglutide (6 mg/mL solution for injection in a 3-mL pre-filled pen (18mg)) versus Insulin Glargine (100 Units/mL solution for injection in a pre-filled SoloStar pen)	Type 2 diabetic patients failing lifestyle management and oral agents	open USA

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>
- antidiabetic drugs for diabetes type 2 in patients inadequately controlled with insulin at <http://www.trialresultscenter.org/go-Q513>

- glucose lowering for cardiovascular prevention for diabetes type 2 in all type of patients at <http://www.trialresultscenter.org/go-Q576>
- glucose lowering for cardiovascular prevention for diabetes type 2 in meta-regression at <http://www.trialresultscenter.org/go-Q692>

## References

### NN2211-1333, :

Harder H, Nielsen L, Tu DT, Astrup A The effect of liraglutide, a long-acting glucagon-like peptide 1 derivative, on glyceimic control, body composition, and 24-h energy expenditure in patients with type 2 diabetes. *Diabetes Care* 2004;27:1915-21 [[15277417](#)]

### LEADER, 2016:

Steinberg WM, Nauck MA, Zinman B, Daniels GH, Bergenstal RM, Mann JF, Steen Ravn L, Moses AC, Stockner M, Baeres FM, Marso SP, Buse JB LEADER 3-lipase and amylase activity in subjects with type 2 diabetes: baseline data from over 9000 subjects in the LEADER Trial. *Pancreas* 2014;43:1223-31 [[25275271](#)]

Petrie JR, Marso SP, Bain SC, Franek E, Jacob S, Masmiquel L, Leiter LA, Haluzik M, Satman I, Omar M, Shestakova M, Van Gaal L, Mann JF, Baeres FM, Zinman B, Poulter NR LEADER-4: blood pressure control in patients with type 2 diabetes and high cardiovascular risk: baseline data from the LEADER randomized trial. *J Hypertens* 2016;: [[26855018](#)]

Masmiquel L, Leiter LA, Vidal J, Bain S, Petrie J, Franek E, Raz I, Comlekci A, Jacob S, van Gaal L, Baeres FM, Marso SP, Eriksson M LEADER 5: prevalence and cardiometabolic impact of obesity in cardiovascular high-risk patients with type 2 diabetes mellitus: baseline global data from the LEADER trial. *Cardiovasc Diabetol* 2016;15:29 [[26864124](#)]

Marso SP, Daniels GH, Brown-Frandsen K, Kristensen P, Mann JF, Nauck MA, Nissen SE, Pocock S, Poulter NR, Ravn LS, Steinberg WM, Stockner M, Zinman B, Bergenstal RM, Buse JB Liraglutide and Cardiovascular Outcomes in Type 2 Diabetes. *N Engl J Med* 2016;: [[27295427](#)]

### Harder, 2004:

Harder H, Nielsen L, Tu DT, Astrup A, The effect of liraglutide, a long-acting glucagon-like peptide 1 derivative, on glyceimic control, body composition, and 24-h energy expenditure in patients with type 2 diabetes. *Diabetes Care* 2004;27:1915-21. [[15277417](#)]

### Kaku 0.6mg, 2010:

Kaku K, Rasmussen MF, Clauson P, Seino Y Improved glycaemic control with minimal hypoglycaemia and no weight change with the once-daily human glucagon-like peptide-1 analogue liraglutide as add-on to sulphonylurea in Japanese patients with type 2 diabetes. *Diabetes Obes Metab* 2010;12:341-7 [[20380655](#)] [10.1111/j.1463-1326.2009.01194.x](#)

### Madsbad (vs placebo), 2004:

Madsbad S, Schmitz O, Ranstam J, Jakobsen G, Matthews DR Improved glyceimic control with no weight increase in patients with type 2 diabetes after once-daily treatment with the long-acting glucagon-like peptide 1 analog liraglutide (NN2211): a 12-week, double-blind, randomized, controlled trial. *Diabetes Care* 2004;27:1335-42 [[15161785](#)]

### NN2211-1571 (Vilsbll), 2007:

Vilsbll T, Zdravkovic M, Le-Thi T, Krarup T, Schmitz O, Courrges JP, Verhoeven R, Bugnov I, Madsbad S Liraglutide, a long-acting human glucagon-like peptide-1 analog, given as monotherapy significantly improves glyceimic control and lowers body weight without risk of hypoglycemia in patients with type 2 diabetes. *Diabetes Care* 2007 Jun;30:1608-10 [[17372153](#)]



Courrges JP, Vilsbll T, Zdravkovic M, Le-Thi T, Krarup T, Schmitz O, Verhoeven R, Bugov I, Madsbad S, Beneficial effects of once-daily liraglutide, a human glucagon-like peptide-1 analogue, on cardiovascular risk biomarkers in patients with Type 2 diabetes. *Diabet Med* 2008;25:1129-31. [19183322] [10.1111/j.1464-5491.2008.02484.x](https://doi.org/10.1111/j.1464-5491.2008.02484.x)

Horowitz M, Vilsbll T, Zdravkovic M, Hammer M, Madsbad S, Patient-reported rating of gastrointestinal adverse effects during treatment of type 2 diabetes with the once-daily human GLP-1 analogue, liraglutide. *Diabetes Obes Metab* 2008;10:593-6. [18435773] [10.1111/j.1463-1326.2008.00861.x](https://doi.org/10.1111/j.1463-1326.2008.00861.x)

**Seino, 2008:**

Seino Y, Rasmussen MF, Zdravkovic M, Kaku K Dose-dependent improvement in glycemia with once-daily liraglutide without hypoglycemia or weight gain: A double-blind, randomized, controlled trial in Japanese patients with type 2 diabetes. *Diabetes Res Clin Pract* 2008;81:161-8 [18495285] [10.1016/j.diabres.2008.03.018](https://doi.org/10.1016/j.diabres.2008.03.018)

**LIBRA, 0:**

ongoing trial NCT01270789

**NCT00978393, 0:**

ongoing trial NCT00978393

**NN2211-1799, 0:**

ongoing trial NCT00620282

**NN2211-1800, 0:**

ongoing trial NCT00943501

**NN2211-3619, 0:**

ongoing trial NCT01206101

**NN8022-1922, 0:**

ongoing trial NCT01272232

**NN8022-1923, 0:**

ongoing trial NCT00781937

**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](https://doi.org/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](https://doi.org/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](https://doi.org/10.3810/pgm.2009.05.1997)

**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](https://doi.org/10.2337/dc08-1355)

**NN2211-1796, 0:**

unpublished

Buse JB, Garber A, Rosenstock J, Schmidt WE, Brett JH, Videbk N, Holst J, Nauck M Liraglutide treatment is associated with a low frequency and magnitude of antibody formation with no apparent impact on glycemic response or increased frequency of adverse events: results from the Liraglutide Effect and Action in Diabetes

(LEAD) trials. J Clin Endocrinol Metab 2011;96:1695-702 [21450987] 10.1210/jc.2010-2822

**NCT01234649, 0:**

ongoing trial NCT01234649

**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-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 sulfonylurea 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 (1.2mg), 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-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

**Kaku 0.9mg, 2010:**

Kaku K, Rasmussen MF, Clauson P, Seino Y Improved glycaemic control with minimal hypoglycaemia and no weight change with the once-daily human glucagon-like peptide-1 analogue liraglutide as add-on to sulphonylurea in Japanese patients with type 2 diabetes. Diabetes Obes Metab 2010;12:341-7 [20380655] 10.1111/j.1463-1326.2009.01194.x

**NN2211-1701, 0:**

ongoing trial NCT00395746

Hegeds L, Moses AC, Zdravkovic M, Le Thi T, Daniels GH GLP-1 and calcitonin concentration in humans: lack of evidence of calcitonin release from sequential screening in over 5000 subjects with type 2 diabetes or nondiabetic obese subjects treated with the human GLP-1 analog, liraglutide. J Clin Endocrinol Metab 2011;96:853-60 [21209033] 10.1210/jc.2010-2318

**MK-0431-403, 0:**

ongoing trial NCT01296412

**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](https://doi.org/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](https://doi.org/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](https://doi.org/10.1111/j.1464-5491.2011.03276.x)

**Seino, 2010:**

Seino Y, Rasmussen MF, Nishida T, Kaku K, Efficacy and safety of the once-daily human GLP-1 analogue, liraglutide, vs glibenclamide monotherapy in Japanese patients with type 2 diabetes. *Curr Med Res Opin* 2010;26:1013-22. [20199137] [10.1185/03007991003672551](https://doi.org/10.1185/03007991003672551)

**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](https://doi.org/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](https://doi.org/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](https://doi.org/10.1111/j.1463-1326.2010.01356.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](https://doi.org/10.1016/S0140-6736(08)61246-5)

**Madsbad (vs Glimepiride), 2004:**

Madsbad S, Schmitz O, Ranstam J, Jakobsen G, Matthews DR Improved glycemic control with no weight increase in patients with type 2 diabetes after once-daily treatment with the long-acting glucagon-like peptide 1 analog liraglutide (NN2211): a 12-week, double-blind, randomized, controlled trial. *Diabetes Care* 2004;27:1335-42 [15161785]

**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](https://doi.org/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](https://doi.org/10.1016/j.pcd.2010.04.001)

Diabetologia 52 (2009) S8.

**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:**

**Feinglos, 2005:**

Feinglos MN, Saad MF, Pi-Sunyer FX, An B, Santiago O Effects of liraglutide (NN2211), a long-acting GLP-1 analogue, on glycaemic control and bodyweight in subjects with Type 2 diabetes. *Diabet Med* 2005;22:1016-23 [[16026367](#)] [10.1111/j.1464-5491.2005.01567.x](#)

**LEAD-1 SU (1.2 vs rosiglitazone), 2009:**

**LEAD-1 SU (1.8 vs rosiglitazone), 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](#)

**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](#)

**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](#)

**EAGLE, 0:**

ongoing trial NCT01117350

Entry terms: liraglutide, victoza