

# 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

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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

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<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

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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>			

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<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

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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>			

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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>

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### **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](#)

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ongoing trial NCT01270789

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ongoing trial NCT00978393

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ongoing trial NCT00620282

**NN2211-1800, 0:**

ongoing trial NCT00943501

**NN2211-3619, 0:**

ongoing trial NCT01206101

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**EAGLE, 0:**

ongoing trial NCT01117350

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