

Clinical trials of insulin secretagogues peptides (incretins) for diabetes type 2 in all type of patients

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1 albiglutide

| Trial | Treatments | Patients | Trials design and methods |
|--|--|---|--|
| albiglutide vs placebo | | | |
| Seino , 2009 [NCT00530309] n=32/8 follow-up: 4 weeks (+5 wk) | albiglutide 15 mg weekly, 30 mg weekly, 50 mg biweekly, and 100 mg monthly versus placebo | Japanese subjects with type 2 diabetes mellitus | Parallel groups single-blind Japan |
| albiglutide biweekly vs placebo (add on MET) | | | |
| Rosenstock (30 mg every two weeks) , 2009 [NCT00518115] n=32/50 follow-up: 16 weeks | albiglutide 30mg weekly versus placebo | patients with type 2 diabetes inadequately controlled with diet and exercise or metformin monotherapy | Parallel groups double blind US, Mexico, Chile, Dominical republic |
| albiglutide weekly vs placebo (add on MET) | | | |
| Rosenstock (30 mg weekly) , 2009 [NCT00518115] n=31/52 follow-up: 16 weeks | albiglutide 30mg weekly versus placebo | patients with type 2 diabetes inadequately controlled with diet and exercise or metformin monotherapy | Parallel groups double-blind US, Mexico, Chile, Dominical republic |
| albiglutide vs liraglutide | | | |
| HARMONY 7 (114179) <i>ongoing</i> [NCT01128894] n=NA follow-up: | weekly albiglutide subcutaneous injection versus liraglutide daily subcutaneous injection, starting at 0.6mg, then up-titrating to 1.2mg then 1.8mg in accordance with prescribing information | subjects with type 2 diabetes | open USA |

References

Seino, 2009:

Seino Y, Nakajima H, Miyahara H, Kurita T, Bush MA, Yang F, Stewart MW, Safety, tolerability, pharmacokinetics and pharmacodynamics of albiglutide, a long-acting GLP-1-receptor agonist, in Japanese subjects with type 2 diabetes mellitus. *Curr Med Res Opin* 2009;25:3049-57. [[19863477](#)] [10.1185/03007990903372999](#)

Rosenstock (30 mg every two weeks), 2009:

Rosenstock J, Reusch J, Bush M, Yang F, Stewart M, , Potential of albiglutide, a long-acting GLP-1 receptor agonist, in type 2 diabetes: a randomized controlled trial exploring weekly, biweekly, and monthly dosing. *Diabetes Care* 2009;32:1880-6. [[19592625](#)] [10.2337/dc09-0366](#)

Rosenstock (30 mg weekly), 2009:

Rosenstock J, Reusch J, Bush M, Yang F, Stewart M, , Potential of albiglutide, a long-acting GLP-1 receptor agonist, in type 2 diabetes: a randomized controlled trial exploring weekly, biweekly, and monthly dosing. *Diabetes Care* 2009;32:1880-6. [[19592625](#)] [10.2337/dc09-0366](#)

HARMONY 7 (114179), 0:

Pratley RE, Nauck MA, Barnett AH, Feinglos MN, Ovalle F, Harman-Boehm I, Ye J, Scott R, Johnson S, Stewart M, Rosenstock J Once-weekly albiglutide versus once-daily liraglutide in patients with type 2 diabetes inadequately controlled on oral drugs (HARMONY 7): a randomised, open-label, multicentre, non-inferiority phase 3 study. *Lancet Diabetes Endocrinol* 2014;2:289-97 [[24703047](#)] [10.1016/S2213-8587\(13\)70214-6](#)

2 glucagon-like peptide 1 receptor agonist

| Trial | Treatments | Patients | Trials design and methods |
|---|---|-------------------------------|---|
| liraglutide vs placebo | | | |
| LEADER , 2016 [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 |

References

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](#)]

3 glucagon-like peptide analogs

| Trial | Treatments | Patients | Trials design and methods |
|--|----------------------------|-------------------------------------|---------------------------|
| liraglutide other doses vs | | | |
| NN2211-1333 n=NA follow-up: | liraglutide versus placebo | obese subjects with type 2 diabetes | |
| exenatide vs glargine | | | |

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| Trial | Treatments | Patients | Trials design and methods |
|---|--|--|---|
| NCT00360334 [NCT00360334] n=118/116 follow-up: | - | - | |
| exenatide 20g vs glibenclamide | | | |
| Derosa , 2010 n=63/65 follow-up: | exenatide 10 microg twice a day versus glibenclamide 5 mg three times a day | patients with uncontrolled type 2 diabetes mellitus receiving therapy with metformin | |
| exenatide vs placebo | | | |
| Liutkus , 2010 n=111/54 follow-up: | exenatide twice-daily versus placebo | subjects suboptimally controlled with TZDs with or without metformin | |
| exenatide 10g/d vs placebo | | | |
| H8O-MC-GWBJ, 9698, 10g/d , 2008 n=NA follow-up: 24 weeks | exenatide twice daily 5 et 10 g for 24 weeks versus placebo | Drug-Naive Patients with Type 2 Diabetes and inadequate glycemic control through diet and exercise | Parallel groups double-blind 4 countries |
| exenatide 20g/d vs placebo | | | |
| Apovian , 2010 n=96/98 follow-up: 24 weeks | 10 microg exenatide twice daily injection + lifestyle modification program versus placebo + lifestyle modification program | overweight or obese participants with type 2 diabetes treated with metformin and/or sulfonylurea | Parallel groups double-blind |
| H8O-MC-GWBJ, 9698, 20g/d , 2008 unpublished n=78/78 follow-up: 24 weeks | exenatide twice daily 10 g for 24 weeks versus placebo | Drug-Naive Patients with Type 2 Diabetes and inadequate glycemic control through diet and exercise | Parallel groups double-blind 4 countries |
| exenatide other doses vs placebo | | | |
| Moretto (DOUBLONS avec druker) , 2008 [NCT00381342] n=155/78 follow-up: 24 weeks | Exenatide 1020 g daily versus Placebo | - | Parallel groups double blind United States, Puerto Rico, Romania, Russia, India |
| NCT00085969 unpublished [NCT00085969] n=99 follow-up: 28 days | exenatide for 28 days versus placebo | subjects with type 2 diabetes mellitus | double-blind USA |
| Poon , 2005 [NCT00044694] n=NA follow-up: 28 days | exenatide at 2.5, 5.0, 7.5, or 10.0 microg administered b.i.d. for 28 days versus placebo | patients with type 2 diabetes | Parallel groups double-blind |
| liraglutide other doses vs placebo | | | |
| Harder , 2004 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 |

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| Trial | Treatments | Patients | Trials design and methods |
|---|---|--|---|
| Kaku 0.6mg , 2010 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 |
| Madsbad (vs placebo) , 2004 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 |
| NN2211-1571 (Vilsbll) , 2007 [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 |
| Seino , 2008 [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 |
| LIBRA ongoing [NCT01270789] n=NA follow-up: 1 year | - | patients with T2DM | double-blind Canada |
| NCT00978393 ongoing [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 |
| NN2211-1799 ongoing [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 |
| NN2211-1800 ongoing [NCT00943501] n=NA follow-up: | - | children with type 2 diabetes | double-blind USA, Europe |
| NN2211-3619 ongoing [NCT01206101] n=NA follow-up: | - | Type 1 Diabetes Undergoing Islet Cell Transplantation | |
| NN8022-1922 ongoing [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 |

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| Trial | Treatments | Patients | Trials design and methods |
|---|--|--|--|
| NN8022-1923 <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 |
| taspoglutide vs placebo | | | |
| BC20750 <i>ongoing</i> [NCT00744926] n=NA follow-up: | taspoglutide 10mg sc once weekly, or taspoglutide 20mg sc once weekly (after 4 weeks of taspoglutide 10mg sc once weekly) versus placebo | patients with type 2 diabetes mellitus inadequately controlled with diet and exercise | double-blind USA |
| BC20963 <i>ongoing</i> [NCT00744367] n=NA follow-up: 24 weeks | taspoglutide 10mg once weekly, taspoglutide 20 mg once weekly (after 4 weeks of taspoglutide 10 mg once weekly) versus placebo in addition to their continued stable metformin plus pioglitazone treatment | patients with type 2 diabetes mellitus inadequately controlled with metformin plus pioglitazone | double-blind USA |
| BC21713 (vs placebo) <i>ongoing</i> [NCT00754988] n=NA follow-up: | taspoglutide (10mg once weekly or 10mg once weekly for 4 weeks followed by 20mg once weekly), versus placebo or sitagliptin 100mg once daily in addition to their continued prestudy metformin treatment | patients with type 2 diabetes mellitus inadequately controlled with metformin | parallel groups double-blind USA |
| BP21572 <i>ongoing</i> [NCT00809705] n=NA follow-up: 12 weeks | 10mg Taspoglutide sc weekly for 12 weeks b)10mg Taspoglutide sc weekly for 4 weeks followed by 20mg Taspoglutide sc weekly for 8 weeks versus placebo | patients with type 2 diabetes | double-blind germany |
| taspoglutide 10mg once weekly vs placebo | | | |
| Nauck 10 once weekly vs PBO , 2009 [NCT00423501] n=257/49 follow-up: 12 weeks | taspoglutide, either 5, 10, or 20 mg once weekly or 10 or 20 mg once every 2 weeks for 8 weeks versus placebo | patients with type 2 diabetes inadequately controlled with metformin | Parallel groups double-blind |
| taspoglutide 20mg once every 2 weeks vs placebo | | | |
| Nauck 20 every 2 weeks vs PBO , 2009 n=NA | - | - | - |
| taspoglutide 20mg once weekly vs placebo | | | |
| Nauck 20 once weekly vs PBO , 2009 n=NA | - | - | - |
| exenatide 20g/d vs placebo (add on insulin) | | | |

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| Trial | Treatments | Patients | Trials design and methods |
|--|--|---|--|
| Buse , 2011 [NCT00765817] n=138/123 follow-up: 30 weeks | twice-daily 10 g exenatide injections versus placebo (on top insulin glargine) | Adults with type 2 diabetes and an HbA1c level of 7.1% to 10.5% who were receiving insulin glargine alone or in combination with metformin or pioglitazone (or both agents) | Parallel groups double-blind Greece, Israel, Mexico, United Kingdom, USA |
| exenatide other doses vs placebo (add on MER+/-SU) | | | |
| Fineman , 2003 n=109 follow-up: 28 days | exenatide 3 regimen (0.08 micro g/kg) for 28 days versus placebo | patients with type 2 diabetes treated with diet and a sulfonylurea and/or metformin | Parallel groups double-blind USA |
| exenatide 10g/d vs placebo (add on MET) | | | |
| DeFronzo 10g/d , 2005 [NCT00039013] n=110/113 follow-up: 30 weeks | Exenatide 1020 g daily versus Placebo on-top of Metformin | patients with type 2 diabetes failing to achieve glycemic control with maximally effective metformin doses | Parallel groups double blind USA |
| exenatide 20g/d vs placebo (add on MET) | | | |
| DeFronzo 20g/d , 2005 [NCT00039013] n=NA follow-up: 30 weeks | Exenatide 1020 g daily versus Placebo on-top of Metformin | patients with type 2 diabetes failing to achieve glycemic control with maximally effective metformin doses | Parallel groups double blind USA |
| exenatide weekly vs placebo (add on MET) | | | |
| Kim , 2007 [NCT00103935] n=30/15 follow-up: 15 weeks | exenatide LAR 0.8 or 2 g daily versus Placebo on-top of metformin | subjects with type 2 diabetes suboptimally controlled with metformin and/or diet and exercise | Parallel groups double blind |
| 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 1.8mg 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 other doses vs placebo (add on MET) | | | |
| NN2211-1796 unpublished [NCT00614120] n=NA follow-up: | liraglutide added to metformin versus glimepiride added to metformin | - | China |
| NCT01234649 ongoing [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 |
|---|---|--|--|
| tasoglutide vs placebo (add on MET) | | | |
| Ratner (20mg once weekly) , 2010 [NCT00460941] n=97/32 follow-up: 8 weeks (+4wk) | tasoglutide s.c. 20mg once weekly for 8 weeks versus placebo s.c. once weekly on top metformin | subjects with Type 2 diabetes inadequately controlled on metformin alone | Parallel groups double-blind Australia, France, Germany, Mexico, Peru, USA |
| BC22092 ongoing [NCT00823992] n=NA follow-up: | tasoglutide (10mg sc once weekly for 4 weeks followed by 20mg once weekly) in addition to their prescribed, pre-existing metformin therapy versus placebo | obese patients with type 2 diabetes mellitus inadequately controlled with metformin monotherapy | parallel groups double-blind USA |
| exenatide 20g/d vs placebo (add on MET+/-SU) | | | |
| Gao , 2009 [NCT00324363] n=234/232 follow-up: 16 weeks | exenatide 5 mg then 10 mg twice-daily for 4 and 12 weeks versus placebo | Asian descent with type 2 diabetes and inadequate glycemic control taking metformin alone or Met and sulfonylureas | Parallel groups double-blind 4 countries |
| exenatide 10g/d vs placebo (add on SU) | | | |
| Buse 10g/d , 2004 [NCT00039026] n=125/123 follow-up: 30 weeks | Exenatide 5g twice daily versus Placebo on-top of SU | patients with type 2 diabetes failing maximally effective doses of a sulfonylurea as monotherapy | Parallel groups double blind (not adequate) US |
| exenatide 20g/d vs placebo (add on SU) | | | |
| Buse 20g/d , 2004 n=129/123 follow-up: 30 weeks | Exenatide 10g twice daily versus Placebo on-top of SU | patients with type 2 diabetes failing maximally effective doses of a sulfonylurea as monotherapy | double blind (not adequate) US |
| 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 1.8mg 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 other doses vs placebo (add on SU) | | | |
| NN2211-1701 ongoing [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 |

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| Trial | Treatments | Patients | Trials design and methods |
|---|---|--|---|
| exenatide 10g/d vs placebo (add on SU+/-MET/TZD) | | | |
| Kadowaki (trial 8683) , 2009 n=111/40 follow-up: 12 weeks | Exenatide 10g daily for 12 weeks versus Placebo on-top of sulphonylureas +/-metformin/thiazolidinediones | Japanese patients with type 2 diabetes suboptimally controlled despite therapeutic dose of sulfonylurea, SU+biguanide or SU+thiazolidinedione | Parallel groups open Japan |
| exenatide 10g/d vs placebo (add on SU+MET) | | | |
| Kendall 10g/d , 2005 [NCT00035984] n=245/247 follow-up: 30 weeks | Exenatide 5 g bid versus Placebo on-top of sulphonylureas+metformin | patients with type 2 diabetes unable to achieve glyceic control with metformin-sulfonylurea combination therapy | Parallel groups double blind USA |
| exenatide 20g/d vs placebo (add on SU+MET) | | | |
| Kendall 20g/d , 2005 [NCT00035984] n=241/247 follow-up: 30 weeks | Exenatide 10 g bid versus Placebo on-top of sulphonylureas+metformin | patients with type 2 diabetes unable to achieve glyceic control with metformin-sulfonylurea combination therapy | Parallel groups double blind USA |
| 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 |
| exenatide 20g/d vs placebo (add on TZD+/-MET) | | | |
| Zinman 20g/j , 2007 [NCT00099320] n=121/112 follow-up: 16 weeks | Exenatide 20 g daily versus Placebo on-top of thiazolidinediones+/-metformin | patients with type 2 diabetes that was suboptimally controlled with TZD treatment (with or without metformin) | double blind Canada, Spain, and the United States |
| Zinman 20g/j A MODIFIER , 2007 n=121/112 follow-up: 16 weeks | exenatide Subcutaneous abdominal injections of 10 microg twice daily versus placebo | patients with type 2 diabetes that was suboptimally controlled with TZD treatment (with or without metformin) | Parallel groups double-blind Canada, Spain, and the United States |
| 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 1.8mg 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 other doses vs placebo (on top SU) | | | |

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| Trial | Treatments | Patients | Trials design and methods |
|---|---|--|--|
| 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 |
| exenatide 10g/d vs placebo add on MET+/-TZD | | | |
| Gill , 2010 n=28/26 follow-up: 12 weeks | exenatide (5 microg for 4 weeks followed by 10 microg) for 12 weeks versus placebo | subjects with type 2 diabetes mellitus on metformin and/or a thiazolidinedione | Parallel groups double-blind |
| tasoglutide vs placebo add on standard treatment | | | |
| NC25113 ongoing [NCT01018173] n=NA follow-up: | tasoglutide subcutaneously (sc) 10mg weekly for 4 weeks followed by 20mg sc weekly in addition to background anti-hyperglycemic medication and standard of care treatment for cardiovascular disease versus placebo | - | parallel groups double-blind USA |
| liraglutide other doses vs sitagliptin (add on MET) | | | |
| MK-0431-403 ongoing [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 |
| exenatide once monthly vs weekly exenatide | | | |
| phase 2 exenatide once monthly unpublished n=121 follow-up: 20 weeks | exenatide once monthly at a low, medium or high dose, each administered once every four weeks, for a total of 20 weeks versus exenatide 2mg once weekly | adults with type 2 diabetes who were not achieving adequate glucose control using diet and exercise alone or with a stable regimen of metformin, pioglitazone, or both | Parallel groups open |
| exenatide 20g/d vs BIAsp 30 daily | | | |
| Bergenstal (once daily) , 2009 n=NA follow-up: 24 weeks | exenatide(5 microg BID for 4 weeks and 10 microg BID thereafter) versus biphasic insulin aspart 70/30 (BIAsp 30) 30 QD (12 U before supper) | subjects with type 2 diabetes mellitus insulin naive, not achieving glycemic targets with metformin and sulfonylurea | Parallel groups open |
| exenatide 20g/d vs BIAsp 30 twice daily | | | |
| Bergenstal (twice daily) , 2009 n=NA follow-up: | exenatide (5 microg BID for 4 weeks and 10 microg BID thereafter) versus biphasic insulin aspart 70/30 (BIAsp 30) 30 BID (12 U divided equally between pre-breakfast and pre-supper) | subjects with type 2 diabetes mellitus insulin naive, not achieving glycemic targets with metformin and sulfonylurea | Parallel groups open |
| tasoglutide vs exenatide | | | |

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| Trial | Treatments | Patients | Trials design and methods |
|--|--|---|--|
| BC21625 <i>ongoing</i> [NCT00717457] n=NA follow-up: | tasoglutide versus exenatide | patients with type 2 diabetes mellitus inadequately controlled with metformin, thiazolidinedione or a combination of both | parallel groups open USA |
| exenatide before lunch and dinner vs exenatide before breakfast and dinner | | | |
| Exenatide Trial 10749 n=187/190 follow-up: | exenatide (10 g twice daily) administered subcutaneously before lunch and dinner versus exenatide (10 g twice daily) administered subcutaneously before breakfast and dinner | patients with type 2 Diabetes using oral antidiabetic therapy | Parallel groups open 2 countries |
| 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 |
| exenatide other doses vs glargine | | | |
| HEELA (Davies) , 2009 n=NA follow-up: | exenatide 5C10 g bid versus insulin glargine o.d. (titrated to target fasting plasma glucose 5.6 mmol/l) | Patients (BMI>27 kg/m ²) with elevated cardiovascular risk and type 2 diabetes inadequately controlled on two or three oral antidiabetes drugs | |
| liraglutide other doses vs glibenclamide | | | |
| Seino , 2010 [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 |
| 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 1.8mg vs glimepiride | | | |
| 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 other doses vs glimepiride | | | |
| Madsbad (vs Glimepiride) , 2004 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 |
|--|---|--|--|
| 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 1.8mg 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 |
| exenatide 20g/d vs insulin (add on SU+MET) | | | |
| Heine , 2005 n=282/267 follow-up: 26 weeks | Exenatide 20 g daily versus Insulin on-top of sulphonylureas+metformin | - | open |
| exenatide 20g/d vs insulin (add on SU/MET) | | | |
| Barnett , 2007 [NCT00099619] n=136/127 follow-up: 16 weeks | Exenatide 20 g daily versus Insulin | patients with type 2 diabetes | Cross over open Australia, Greece,Hungary, Italy, Mexico, and Poland |
| Davis , 2007 [NCT00099333] n=33/16 follow-up: 16 weeks | Exenatide 20 g daily versus Insulin on-top of sulphonylureas/metformin | patients with type 2 diabetes using insulin in combination with oral antidiabetes agents | Parallel groups open USA |
| exenatide 20g/d vs insulin BIAsp twice daily add on SU+MET | | | |
| Nauck , 2007 [NCT00082407] n=253/248 follow-up: 52 weeks | Exenatide 20 g daily versus Insulin on-top of sulphonylureas+metformin | patients with type 2 diabetes who were suboptimally controlled with sulfonyleurea and metformin | Parallel groups open 13 countries |
| exenatide weekly vs insulin glargine | | | |
| DURATION-3 (Diamant) , 2010 [NCT00641056] n=233/223 follow-up: 26 weeks | exenatide (2 mg, once-a-week injection) versus insulin glargine once-daily injection | adults with type 2 diabetes who had suboptimum glycaemic control despite use of maximum tolerated doses of blood-glucose-lowering drugs for 3 months or longer | Parallel groups open (blind analysis) USA, Puerto Rico, Europe, Russia, Australia, Korea, Taiwan, Mexico |
| liraglutide other doses vs insulin glargine | | | |
| EAGLE <i>ongoing</i> [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 |
| tasoglutide vs insulin glargine | | | |

continued...

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| ZC22565 <i>ongoing</i> [NCT01051011] n=NA follow-up: | tasoglutide 10mg subcutaneously (sc) weekly, or tasoglutide 10mg sc weekly for 4 weeks followed by 20mg sc weekly versus insulin glargine at an initial dose of 10 international units sc daily | insulin-naive patients with type 2 diabetes mellitus inadequately controlled on metformin and sulfonylurea combination therapy | parallel groups open China |
| exenatide 20g/d vs insulin glargine (add on MET) | | | |
| Bunck , 2009 [NCT00097500] n=36/33 follow-up: 52 weeks | exenatide 10g bid versus insulin glargine | metformin-treated patients with type 2 diabetes | Parallel groups |
| tasoglutide vs insulin glargine (add on MET) | | | |
| BC20965 <i>ongoing</i> [NCT00755287] n=NA follow-up: 2 years | tasoglutide (10 mg once weekly, or 10mg once weekly for 4 weeks followed by 20mg once weekly) versus insulin glargine (starting dose 10 IU/day) in addition to continued prestudy metformin treatment | patients with insulin-naive type 2 diabetes mellitus inadequately controlled with metformin and sulphonylurea combination therapy | open USA |
| exenatide other doses vs insulin glargine (add on MET/SU) | | | |
| Trial 8078 n=NA follow-up: | exenatide versus Insulin Glargine | Patients with Type 2 Diabetes Using Metformin or Sulfonylurea for Whom Insulin Is the Next Appropriate Therapy | |
| 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 |
| exenatide weekly vs liraglutide | | | |
| H8O-MC-GWDE <i>ongoing</i> [NCT01029886] n=NA follow-up: 36 weeks | exenatide once weekly for 26 weeks versus once-daily liraglutide for 26 weeks | - | open argentina |
| 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 | - | - | |
| exenatide 10g twice daily vs liraglutide 1.8mg | | | |

continued...

| Trial | Treatments | Patients | Trials design and methods |
|--|--|---|---|
| LEAD 6 (Buse) exe vs lira , 2009 n=NA | - | - | |
| liraglutide other doses vs metformin | | | |
| 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) |
| exenatide weekly vs pioglitazone | | | |
| DURATION-2 (Bergental) (vs pioglitazone) , 2010 [NCT00637273] n=170/172 follow-up: 26 weeks | 2 mg injected exenatide once weekly plus oral placebo once daily versus 45 mg oral pioglitazone once daily plus injected placebo once weekly | - | Parallel groups double blind USA, India, and Mexico |
| taspoglutide vs pioglitazone | | | |
| BC21893 <i>ongoing</i> [NCT00909597] n=NA follow-up: 24 months | taspoglutide 10mg sc weekly, or taspoglutide 20mg sc weekly after 4 weeks of taspoglutide 10mg sc weekly versus pioglitazone 45mg/day po after 4 weeks of pioglitazone 30mg/day po | patients with type 2 diabetes mellitus inadequately controlled with sulfonylurea monotherapy or sulfonylurea plus metformin combination therapy | parallel groups double-blind USA |
| liraglutide 1.2mg vs rosiglitazone | | | |
| LEAD-1 SU (1.2 vs rosiglitazone) , 2009 n=NA | - | - | |
| liraglutide other doses vs rosiglitazone (add on SU) | | | |
| LEAD-1 SU (1.8 vs rosiglitazone) , 2009 [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 |
| exenatide 20g/d vs rosiglitazone add on MET | | | |
| DeFronzo (EXE vs ROSI) , 2010 n=45/45 follow-up: 20 weeks | EXE 10 microg b.i.d. versus ROSI 4 mg b.i.d. | subjects with type 2 diabetes on metformin | Parallel groups open |
| exenatide weekly vs sitagliptin | | | |
| DURATION-2 (Bergental) (vs sitagliptin) , 2010 [NCT00637273] n=170 follow-up: 26 weeks | 2 mg injected exenatide once weekly plus oral placebo once daily versus 100 mg oral sitagliptin once daily plus injected placebo once weekly | patients treated with metformin | double blind USA, India, and Mexico |
| liraglutide 1.2mg vs sitagliptin | | | |

continued...

| Trial | Treatments | Patients | Trials design and methods |
|--|---|---|--|
| 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 |
| 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 |
| exenatide 20g/d vs sitagliptin (add on MET) | | | |
| DeFronzo , 2008 [NCT00477581] n=NA follow-up: 2 weeks | exenatide subcutaneous injection versus sitagliptin (100 mg QAM) for 2 weeks | metformin-treated T2D patients | Cross over double-blind USA |
| exenatide 20g/d vs weekly exenatide | | | |
| Drucker , 2008 [NCT00308139] n=NA follow-up: 30 weeks | 10 mug exenatide administered twice a day versus long-acting release formulation of exenatide 2 mg administered once weekly | patients with type 2 diabetes naive to drug therapy, or on one or more oral antidiabetic agents | Parallel groups open |

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4 lixisenatide

| Trial | Treatments | Patients | Trials design and methods |
|--|---|---|--|
| lixisenatide vs control | | | |
| GETGOAL-MONO Japan <i>LTS ongoing</i> [NCT00905255] n=NA follow-up: 24-76 weeks | AVE0010 once daily treatment in monotherapy versus usual care | type 2 diabetes patients | Parallel groups open Japan |
| lixisenatide vs placebo | | | |
| ELIXA (EFC11319) <i>ongoing</i> [NCT01147250] n=NA follow-up: | Lixisenatide 20 g one daily versus placebo | type 2 diabetic patients who experienced an acute coronary syndrome | double-blind USA |
| GETGOAL-MONO <i>ongoing</i> [NCT00688701] n=NA follow-up: 12 weeks | AVE0010 in monotherapy versus lixisenatide | Type 2 diabetes mellitus not treated with any antidiabetic agent | Parallel groups double-blind USA |
| lixisenatide vs placebo (add on basal insulin) | | | |
| GETGOAL-L <i>unpublished</i> [NCT00715624] n=328/167 follow-up: 24 weeks | AVE0010 (10,15 and 20 g) in association with basal insulin, with or without metformin versus placebo on top basal insulin | Type 2 diabetes mellitus insufficiently controlled with basal insulin with or without metformin | double-blind USA |
| GetGoal Duo1 <i>ongoing</i> [NCT00975286] n=NA follow-up: 24 weeks | Lixisenatide as an add-on treatment to insulin glargine and metformin versus placebo | patients with type 2 diabetes insufficiently controlled with insulin glargine and metformin | Parallel groups double-blind USA |

continued...

| Trial | Treatments | Patients | Trials design and methods |
|---|--|---|--|
| GETGOAL-L-ASIA <i>ongoing</i> [NCT00866658] n=NA follow-up: 24 weeks | 24 weeks of AVE0010 versus placebo on Top of Basal Insulin +/- Sulfonylurea | Patients With Type 2 Diabetes Insufficiently Controlled With Basal Insulin With or Without Sulfonylurea | double-blind Japan |
| lixisenatide vs placebo (add on MET) | | | |
| Ratner DRI6012 , 2010 [NCT00299871] n=433/109 follow-up: 13 weeks | subcutaneous lixisenatide doses of 5, 10, 20 or 30 microg once daily or twice daily versus placebo | patients with Type 2 diabetes inadequately controlled with metformin (\geq 1000 mg/day) | Parallel groups double-blind (nature not volume) multinational |
| GETGOAL-F1 <i>ongoing</i> [NCT00763451] n=NA follow-up: 24 weeks | AVE0010 in association with metformin versus placebo | Type 2 diabetes mellitus insufficiently controlled with metformin | double-blind USA |
| GETGOAL-M <i>ongoing</i> [NCT00712673] n=NA follow-up: 24 weeks | - | Type 2 diabetes mellitus insufficiently controlled with metformin | Parallel groups double-blind USA |
| lixisenatide vs placebo (add on MET +/-SU) | | | |
| GetGoal-M-As <i>ongoing</i> [NCT01169779] n=NA follow-up: 24 weeks | Lixisenatide (Titration phase: 10 g maintenance phase: 20 g, add-on treatment to metformin with or without sulfonylurea versus add-on treatment to metformin with or without sulfonylurea | - | double-blind China |
| lixisenatide vs placebo (add on SU +/-MET) | | | |
| GETGOAL-S <i>ongoing</i> [NCT00713830] n=NA follow-up: 24 weeks | AVE0010 in association with sulfonylurea without or with metformin versus placebo | patients with type 2 diabetes not adequately controlled with sulfonylurea | double-blind USA |
| lixisenatide vs placebo (add on TZD +/-MET) | | | |
| GETGOAL-P <i>ongoing</i> [NCT00763815] n=NA follow-up: 24 weeks | AVE0010 in association with pioglitazone with or without metformin versus placebo | Type 2 diabetes mellitus insufficiently controlled with pioglitazone with or without metformin | Parallel groups double-blind USA |
| lixisenatide vs exenatide | | | |
| GetGoal-X <i>ongoing</i> [NCT00707031] n=NA follow-up: 24 weeks | AVE0010 in association with metformin versus exenatide in association with metformin | type 2 diabetes | parallel groups open USA |
| lixisenatide vs sitagliptin (add on MET) | | | |
| EFC10780 , 2010 <i>ongoing</i> [NCT00976937] n=NA follow-up: 24 weeks | Lixisenatide titrated 15-20 g once daily versus Sitagliptin (add-on to Metformin) | Obese Type 2 Diabetic Patients Younger Than 50 | Parallel groups double-blind WW |

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GETGOAL-M, 0:

GetGoal-M-As, 0:

GETGOAL-S, 0:

GETGOAL-P, 0:

GetGoal-X, 0:

EFC10780, 2010:

5 About TrialResults-center.org

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