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

TrialResults-center www.trialresultscenter.org

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) *ongoing* [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

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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, Netherlans
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 Afria, Asia, Europe and the United States of America

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Trial	Treatments	Patients	Trials design and methods
NN8022-1923 *ongoing* [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 *ongoing* [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 *ongoing* [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) *ongoing* [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 *ongoing* [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 tyep 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
taspoglutide vs placebo (add on MET)			
Ratner (20mg once weekly) , 2010 [NCT00460941] n=97/32 follow-up: 8 weeks (+4wk)	taspoglutide 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:	taspoglutide (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 desccent 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 glycemic 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 glycemic 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
taspoglutide vs placebo add on standard treatment			
NC25113 *ongoing* [NCT01018173] n=NA follow-up:	taspoglutide 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
taspoglutide vs exenatide			

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Trial	Treatments	Patients	Trials design and methods
BC21625 *ongoing* [NCT00717457] n=NA follow-up:	taspoglutide 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/m2) 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 sulfonylurea 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 *ongoing* [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
taspoglutide vs insulin glargine			

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Trial	Treatments	Patients	Trials design and methods
ZC22565 *ongoing* [NCT01051011] n=NA follow-up:	taspoglutide 10mg subcutaneously (sc) weekly, or taspoglutide 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-nave patients with type 2 diabetes mellitus inadequately controlled on merformin 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
taspoglutide vs insulin glargine (add on MET)			
BC20965 *ongoing* [NCT00755287] n=NA follow-up: 2 years	taspoglutide (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 *ongoing* [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			

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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 (Bergenstal) (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 *ongoing* [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 rosiflitazone			
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 (Bergenstal) (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			

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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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NN2211-3619, 0:

NN8022-1922, 0:

NN8022-1923, 0:

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BC20963, 0:

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4 lixisenatide

Trial	Treatments	Patients	Trials design and methods
lixisenatide vs control			
GETGOAL-MONO Japan LTS *ongoing* [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) *ongoing* [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 *ongoing* [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 *unpublished* [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 *ongoing* [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 *ongoing* [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 (>= 1000 mg/day)	Parallel groups double-blind (nature not volume) multinational
GETGOAL-F1 *ongoing* [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 *ongoing* [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 *ongoing* [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 *ongoing* [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 *ongoing* [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 *ongoing* [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 *ongoing* [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-S, 0:
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GetGoal-X, 0:
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5 About TrialResults-center.org

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