

Clinical trials of exenatide

TrialResults-center www.trialresultscenter.org

1 diabetes type 2

Trial	Treatments	Patients	Trials design and methods
exenatide vs glargine			
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	
EXSCEL ongoing [NCT01144338] n=NA	-	-	
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 sulfonyleurea	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H8O-MC-GWBJ, 9698, 20g/d , 2008 unpublished n=78/78 follow-up: 24 weeks	exenatide twice daily 10 g for 24 weeks versus placebo	Drug-Naive Patients with Type 2 Diabetes and inadequate glycemic control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

continued...

Trial	Treatments	Patients	Trials design and methods
exenatide other doses vs placebo			
Moretto (DOUBLONS avec drucker) , 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 <i>unpublished</i> [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
exenatide 20g/d vs placebo (add on insulin)			
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)			

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Trial	Treatments	Patients	Trials design and methods
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
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
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
exenatide 20g/d vs placebo (add on TZD+/-MET)			

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Trial	Treatments	Patients	Trials design and methods
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
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
exenatide once monthly vs weekly exenatide			
phase 2 exenatide once monthly <i>unpublished</i> 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 sulfonyleurea	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 sulfonyleurea	Parallel groups open
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

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Trial	Treatments	Patients	Trials design and methods
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	
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
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
exenatide other doses vs insulin glargine (add on MET/SU)			

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Trial	Treatments	Patients	Trials design and methods
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	

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>

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Trial 8078, :

Entry terms: nouveau, exenatide, exendin 4, exendin-4, Ex4 peptide, Byetta, AC 2993, AC 2993 LAR,