

# Clinical trials of lixisenatide

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

## 1 diabetes type 2

Trial	Treatments	Patients	Trials design and methods
<b>lixisenatide vs glargine once daily</b>			
<b>GETGOAL-L</b> <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unpublished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	Parallel groups double-blind USA
<b>lixisenatide vs placebo (add on MET)</b>			
<b>Ratner DRI6012</b> , 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
<b>GETGOAL-F1</b> <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
<b>GETGOAL-M</b> <i>ongoing</i> [NCT00712673] n=NA follow-up: 24 weeks	-	Type 2 diabetes mellitus insufficiently controlled with metformin	Parallel groups double-blind USA
<b>lixisenatide vs control</b>			
<b>GETGOAL-MONO Japan LTS</b> <i>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
<b>lixisenatide vs placebo</b>			
<b>ELIXA</b> [NCT01147250] n=6068 follow-up: 25 months (median)	lixisenatide versus placebo	patients with T2DM and a recent ACS event	double-blind 49 countries

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>ELIXA (EFC11319)</b> <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
<b>GETGOAL-MONO</b> <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
<b>lixisenatide vs placebo (add on basal insulin)</b>			
<b>GETGOAL-L</b> <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unpublished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
<b>GetGoal Duo1</b> <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
<b>GETGOAL-L-ASIA</b> <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
<b>lixisenatide vs placebo (add on MET+/-SU)</b>			
<b>GetGoal-M-As</b> <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
<b>lixisenatide vs placebo (add on SU+/-MET)</b>			
<b>GETGOAL-S</b> <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
<b>lixisenatide vs placebo (add on TZD+/-MET)</b>			

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>GETGOAL-P</b> <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
<b>lixisenatide vs exenatide</b>			
<b>GetGoal-X</b> <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
<b>lixisenatide vs sitagliptin (add on MET)</b>			
<b>EFC10780 , 2010</b> <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

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>
- insulin therapy for diabetes type 2 in all type of patients at <http://www.trialresultscenter.org/go-Q548>
- glucose lowering for cardiovascular prevention for diabetes type 2 in all type of patients at <http://www.trialresultscenter.org/go-Q576>
- glucose lowering for cardiovascular prevention for diabetes type 2 in meta-regression at <http://www.trialresultscenter.org/go-Q692>

## References

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### **Ratner DRI6012, 2010:**

Ratner RE, Rosenstock J, Boka G Dose-dependent effects of the once-daily GLP-1 receptor agonist lixisenatide in patients with Type 2 diabetes inadequately controlled with metformin: a randomized, double-blind, placebo-controlled trial. *Diabet Med* 2010;27:1024-32 [[20722676](#)] [10.1111/j.1464-5491.2010.03020.x](#)

### **GETGOAL-F1, 0:**

ongoing trial NCT00763451

### **GETGOAL-M, 0:**

ongoing trial NCT00712673

### **GETGOAL-MONO Japan LTS, 0:**

ongoing trial NCT00905255

### **ELIXA, :**

Bentley-Lewis R, Aguilar D, Riddle MC, Claggett B, Diaz R, Dickstein K, Gerstein HC, Johnston P, Kber LV, Lawson F, Lewis EF, Maggioni AP, McMurray JJ, Ping L, Probstfield JL, Solomon SD, Tardif JC, Wu Y, Pfeffer MA Rationale, design, and baseline characteristics in Evaluation of LIXisenatide in Acute Coronary Syndrome, a long-term cardiovascular end point trial of lixisenatide versus placebo. *Am Heart J* 2015;169:631-638.e7 [[25965710](#)]

Pfeffer MA, Claggett B, Diaz R, Dickstein K, Gerstein HC, Kber LV, Lawson FC, Ping L, Wei X, Lewis EF, Maggioni AP, McMurray JJ, Probstfield JL, Riddle MC, Solomon SD, Tardif JC Lixisenatide in Patients with Type 2 Diabetes and Acute Coronary Syndrome. *N Engl J Med* 2015;373:2247-57 [[26630143](#)]

Pfeffer MA, Claggett B, Diaz R, Dickstein K, Gerstein HC, Kber LV, Lawson FC, Ping L, Wei X, Lewis EF, Maggioni AP, McMurray JJ, Probstfield JL, Riddle MC, Solomon SD, Tardif JC Lixisenatide in Patients with Type 2 Diabetes and Acute Coronary Syndrome. *N Engl J Med* 2015;373:2247-57 [[26630143](#)]

### **ELIXA (EFC11319), 0:**

ongoing trial NCT01147250

### **GETGOAL-MONO, 0:**

ongoing trial NCT00688701

Fonseca VA, Alvarado-Ruiz R, Raccach D, Boka G, Miossec P, Gerich JE Efficacy and Safety of the Once-Daily GLP-1 Receptor Agonist Lixisenatide in Monotherapy: A randomized, double-blind, placebo-controlled trial in patients with type 2 diabetes (GetGoal-Mono). *Diabetes Care* 2012;: [[22432104](#)] [10.2337/dc11-1935](#)

### **GETGOAL-L, 0:**

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### **GetGoal Duo1, 0:**

ongoing trial NCT00975286

[10.2337/dc12-2462](#)

### **GETGOAL-L-ASIA, 0:**

ongoing trial NCT00866658

### **GetGoal-M-As, 0:**

ongoing trial NCT01169779

### **GETGOAL-S, 0:**

ongoing trial NCT00713830

**GETGOAL-P, 0:**

ongoing trial NCT00763815

**GetGoal-X, 0:**

ongoing trial NCT00707031

**EFC10780, 2010:**

ongoing trial NCT00976937

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