

# Clinical trials of taspoglutide

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## 1 diabetes type 2

Trial	Treatments	Patients	Trials design and methods
<b>taspoglutide 10mg once weekly vs placebo</b>			
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
<b>taspoglutide 20mg once every 2 weeks vs placebo</b>			
Nauck 20 every 2 weeks vs PBO , 2009 n=NA	-	-	
<b>taspoglutide 20mg once weekly vs placebo</b>			
Nauck 20 once weekly vs PBO , 2009 n=NA	-	-	
<b>taspoglutide vs placebo</b>			
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

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>BC21713 (vs placebo)</b> <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
<b>BP21572</b> <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
<b>NCT01018173</b> <i>ongoing</i> [NCT01018173] n=NA	-	-	
<b>taspoglutide vs placebo (add on MET)</b>			
<b>Ratner (20mg once weekly)</b> , 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
<b>BC22092</b> <i>ongoing</i> [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
<b>taspoglutide vs placebo add on standard treatment</b>			
<b>NC25113</b> <i>ongoing</i> [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
<b>taspoglutide vs exenatide</b>			

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>BC21625</b> <i>ongoing</i> [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
<b>taspoglutide vs insulin glargine</b>			
<b>ZC22565</b> <i>ongoing</i> [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-naive patients with type 2 diabetes mellitus inadequately controlled on merformin and sulfonylurea combination therapy	parallel groups open China
<b>taspoglutide vs insulin glargine (add on MET)</b>			
<b>BC20965</b> <i>ongoing</i> [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
<b>taspoglutide vs pioglitazone</b>			
<b>BC21893</b> <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

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>

## References

### **Nauck 10 once weekly vs PBO, 2009:**

Nauck MA, Ratner RE, Kapitza C, Berria R, Boldrin M, Balena R, Treatment with the human once-weekly glucagon-like peptide-1 analog taspoglutide in combination with metformin improves glycemic control and lowers body weight in patients with type 2 diabetes inadequately controlled with metformin alone: a double-blind placebo-controlled study. Diabetes Care 2009;32:1237-43. [19366970] 10.2337/dc08-1961

### **Nauck 20 every 2 weeks vs PBO, 2009:**

### **Nauck 20 once weekly vs PBO, 2009:**

#### **BC20750, 0:**

ongoing trial NCT00744926

#### **BC20963, 0:**

ongoing trial NCT00744367

#### **BC21713 (vs placebo), 0:**

ongoing trial NCT00754988

#### **BP21572, 0:**

ongoing trial NCT00809705

#### **NCT01018173, :**

ongoing trial NCT01018173

### **Ratner (20mg once weekly), 2010:**

Ratner R, Nauck M, Kapitza C, Asnaghi V, Boldrin M, Balena R, Safety and tolerability of high doses of taspoglutide, a once-weekly human GLP-1 analogue, in diabetic patients treated with metformin: a randomized double-blind placebo-controlled study. Diabet Med 2010;27:556-62. [20536952] 10.1111/j.1464-5491.2010.02990.x

#### **BC22092, 0:**

ongoing trial NCT00823992

#### **NC25113, 0:**

ongoing trial NCT01018173

#### **BC21625, 0:**

ongoing trial NCT00717457

#### **ZC22565, 0:**

ongoing trial NCT01051011

#### **BC20965, 0:**

ongoing trial NCT00755287

**BC21893, 0:**

ongoing trial NCT00909597

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