Trial record **1 of 1** for: gwco

Previous Study | Return to List | Next Study

Addition Of Exenatide To Insulin Glargine In Type 2 Diabetes Mellitus

ClinicalTrials.gov Identifier: NCT00765817

Recruitment Status: Completed
First Posted: October 3, 2008
Results First Posted: January 26, 2011
Last Update Posted: October 24, 2016

Sponsor:
AstraZeneca

Collaborator:
Eli Lilly and Company

Information provided by (Responsible Party):
AstraZeneca

Study Details | Tabular View | Study Results | Disclaimer

How to Read a Study Record

Study Type:	Interventional

Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Double (Participant, Investigator); Primary Purpose: Treatment
Condition:	Type 2 Diabetes
Interventions:	Drug: placebo Drug: exenatide

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Two subjects who started the study, subsequently withdrew prior to receiving study medication and are not part of the full analysis set

Reporting Groups

	Description
Exenatide Arm	Exenatide 5mcg twice daily for 4 weeks, followed by exenatide 10mcg twice daily for 26 weeks (with a background of titrated insulin glargine and other oral antidiabetic agents)
Placebo Arm	Placebo volume equivalent to the active volume injected in the exenatide arm (with a background of titrated insulin glargine and other oral antidiabetic agents)

Participant Flow: Overall Study

	Exenatide Arm	Placebo Arm
STARTED	**138** [1]	**123** [1]
COMPLETED	**112**	**101**
NOT COMPLETED	**26**	**22**
Adverse Event	**13**	**1**
Death	**0**	**1**
Entry criteria not met	**2**	**2**
Loss of glucose control	**0**	**2**
Lost to Follow-up	**1**	**3**
Physician Decision	**2**	**1**
Protocol Violation	**1**	**1**
Subject decision	**7**	**11**

[1] One subject withdrew prior to receiving study medication, not included in analysis set

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
One subject per group withdrew from the study prior to the first dose of study medication and therefore are not part of the baseline or subsequent analysis.

Reporting Groups

	Description
Exenatide Arm	Exenatide 5mcg twice daily for 4 weeks, followed by exenatide 10mcg twice daily for 26 weeks (with a background of titrated insulin glargine and other oral antidiabetic agents)
Placebo Arm	

	Placebo volume equivalent to the active volume injected in the exenatide arm (with a background of titrated insulin glargine and other oral antidiabetic agents)
Total	Total of all reporting groups

Baseline Measures

	Exenatide Arm	Placebo Arm	Total
Overall Participants Analyzed [Units: Participants]	**137**	**122**	**259**
Age [Units: Participants]			
<=18 years	**0**	**0**	**0**
Between 18 and 65 years	**100**	**84**	**184**
>=65 years	**37**	**38**	**75**
Age [Units: Years] Mean (Standard Deviation)	**58.67 (8.91)**	**59.40 (9.96)**	**59.01 (9.41)**
Gender [Units: Participants]			
Female	**67**	**44**	**111**
Male	**70**	**78**	**148**

Outcome Measures

Hide All Outcome Measures

1. Primary: Change in Glycosylated Hemoglobin (HbA1c) [Time Frame: baseline and 30 weeks]

Measure Type	Primary
Measure Title	Change in Glycosylated Hemoglobin (HbA1c)
Measure Description	

	Change in HbA1c from baseline following 30 weeks of therapy (i.e., HbA1c at week 30 minus HbA1c at baseline). Unit of measure is percent of hemoglobin that is glycosylated.
Time Frame	baseline and 30 weeks

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Only patients with non-missing baseline value and at least one non-missing post-baseline value of the response variable were included in analysis

Reporting Groups

	Description
Exenatide Arm	Exenatide 5mcg twice daily for 4 weeks, followed by exenatide 10mcg twice daily for 26 weeks (with a background of titrated insulin glargine and other oral antidiabetic agents)
Placebo Arm	Placebo volume equivalent to the active volume injected in the exenatide arm (with a background of titrated insulin glargine and other oral antidiabetic agents)

Measured Values

	Exenatide Arm	**Placebo Arm**
Participants Analyzed	**112**	**100**
Change in Glycosylated Hemoglobin (HbA1c) [Units: Percentage of hemoglobin] Least Squares Mean (Standard Error)	**-1.71 (0.09)**	**-1.00 (0.09)**

Statistical Analysis 1 for Change in Glycosylated Hemoglobin (HbA1c)

Groups [1]	All groups
Statistical Test Type [2]	Superiority or Other

Statistical Method [3]	ANCOVA
P Value [4]	<0.001

[1] Additional details about the analysis, such as null hypothesis and power calculation:

No text entered.

[2] Details of power calculation, definition of non-inferiority margin, and other key parameters:

No text entered.

[3] Other relevant method information, such as adjustments or degrees of freedom:

No text entered.

[4] Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

No text entered.

2. Secondary: Percentage of Patients Achieving HbA1c <=7% [Time Frame: baseline and 30 weeks]

Measure Type	Secondary
Measure Title	Percentage of Patients Achieving HbA1c <=7%
Measure Description	Percentage of patients in each arm who had HbA1c >7% at baseline and had HbA1c <=7% at week 30 (percentage = [number of subjects with HbA1c <=7% at week 30 divided by number of subjects with HbA1c >7% at baseline] * 100%).
Time Frame	baseline and 30 weeks

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set. Last observation carried forward. Only patients with non-missing baseline value and at least one non-missing post-baseline value of the response variable were included in analysis. Only patients with baseline HbA1c > target were included in calculation.

Reporting Groups

	Description
Exenatide Arm	Exenatide 5mcg twice daily for 4 weeks, followed by exenatide 10mcg twice daily for 26 weeks (with a background of titrated insulin glargine and other oral antidiabetic agents)
Placebo Arm	Placebo volume equivalent to the active volume injected in the exenatide arm (with a background of titrated insulin glargine and other oral antidiabetic agents)

Measured Values

	Exenatide Arm	Placebo Arm
Participants Analyzed	**127**	**106**
Percentage of Patients Achieving HbA1c <=7% [Units: Percentage]	**58.3**	**31.1**

Statistical Analysis 1 for Percentage of Patients Achieving HbA1c <=7%

Groups [1]	All groups
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	Cochran-Mantel-Haenszel
P Value [4]	<0.001

[1] Additional details about the analysis, such as null hypothesis and power calculation:

No text entered.

[2] Details of power calculation, definition of non-inferiority margin, and other key parameters:

No text entered.

[3] Other relevant method information, such as adjustments or degrees of freedom:

No text entered.

[4] Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

No text entered.

3. Secondary: Percentage of Patients Achieving HbA1c <=6.5% [Time Frame: baseline and 30 weeks]

Measure Type	Secondary
Measure Title	Percentage of Patients Achieving HbA1c <=6.5%
Measure Description	Percentage of patients in each arm who had HbA1c >6.5% at baseline and had HbA1c <=6.5% at week 30 (percentage = [number of subjects with HbA1c <=6.5% at week 30 divided by number of subjects with HbA1c >6.5% at baseline] * 100%).
Time Frame	baseline and 30 weeks

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set. Last observation carried forward. Only patients with non-missing baseline value and at least one non-missing post-baseline value of the response variable were included in analysis. Only patients with baseline HbA1c > target were included in calculation.

Reporting Groups

	Description
Exenatide Arm	Exenatide 5mcg twice daily for 4 weeks, followed by exenatide 10mcg twice daily for 26 weeks (with a background of titrated insulin glargine and other oral antidiabetic agents)
Placebo Arm	Placebo volume equivalent to the active volume injected in the exenatide arm (with a background of titrated insulin glargine and other oral antidiabetic agents)

Measured Values

	Exenatide Arm	**Placebo Arm**

Participants Analyzed	**131**	**113**
Percentage of Patients Achieving HbA1c <=6.5% [Units: Percentage]	**42.0**	**13.3**

Statistical Analysis 1 for Percentage of Patients Achieving HbA1c <=6.5%

Groups [1]	All groups
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	Cochran-Mantel-Haenszel
P Value [4]	<0.001

[1] Additional details about the analysis, such as null hypothesis and power calculation:

No text entered.

[2] Details of power calculation, definition of non-inferiority margin, and other key parameters:

No text entered.

[3] Other relevant method information, such as adjustments or degrees of freedom:

No text entered.

[4] Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

No text entered.

4. Secondary: Change in Fasting Serum Glucose [Time Frame: baseline and 30 weeks]

Measure Type	Secondary
Measure Title	Change in Fasting Serum Glucose
Measure Description	Change in fasting serum glucose following 30 weeks of therapy (i.e., fasting serum glucose at week 30 minus fasting serum glucose at baseline)
Time Frame	baseline and 30 weeks

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set, Only patients with non-missing baseline value and at least one non-missing post-baseline value of the response variable were included in analysis

Reporting Groups

	Description
Exenatide Arm	Exenatide 5mcg twice daily for 4 weeks, followed by exenatide 10mcg twice daily for 26 weeks (with a background of titrated insulin glargine and other oral antidiabetic agents)
Placebo Arm	Placebo volume equivalent to the active volume injected in the exenatide arm (with a background of titrated insulin glargine and other oral antidiabetic agents)

Measured Values

	Exenatide Arm	**Placebo Arm**
Participants Analyzed	**111**	**98**
Change in Fasting Serum Glucose [Units: mmol/L] Least Squares Mean (Standard Error)	**-1.28 (0.2)**	**-0.87 (0.2)**

Statistical Analysis 1 for Change in Fasting Serum Glucose

Groups [1]	All groups
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	ANCOVA
P Value [4]	0.174

[1] Additional details about the analysis, such as null hypothesis and power calculation:

No text entered.

[2] Details of power calculation, definition of non-inferiority margin, and other key parameters:

No text entered.

[3] Other relevant method information, such as adjustments or degrees of freedom:

No text entered.

[4] Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

No text entered.

5. Secondary: Change in 7-point Self-monitored Blood Glucose (SMBG) Profile [Time Frame: baseline and 30 weeks]

Measure Type	Secondary
Measure Title	Change in 7-point Self-monitored Blood Glucose (SMBG) Profile
Measure Description	Change in 7-point (pre-breakfast, 2 hour post-breakfast, pre-lunch, 2 hour post-lunch, pre-dinner, 2 hour post-dinner, 0300 hours) SMBG profile from baseline to week 30 (change = blood glucose value at week 30 minus blood glucose value at baseline)
Time Frame	baseline and 30 weeks

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set, Only patients with non-missing baseline value and at least one non-missing post-baseline value of the response variable were included in analysis

Reporting Groups

	Description
Exenatide Arm	Exenatide 5mcg twice daily for 4 weeks, followed by exenatide 10mcg twice daily for 26 weeks (with a background of titrated insulin glargine and other oral antidiabetic agents)

Placebo Arm	Placebo volume equivalent to the active volume injected in the exenatide arm (with a background of titrated insulin glargine and other oral antidiabetic agents)

Measured Values

	Exenatide Arm	Placebo Arm
Participants Analyzed	**108**	**89**
Change in 7-point Self-monitored Blood Glucose (SMBG) Profile [Units: mmol/L] Least Squares Mean (Standard Error)		
Pre-breakfast: baseline	**7.89 (0.2)**	**8.27 (0.2)**
Pre-breakfast: change at week 30	**-1.58 (0.1)**	**-1.48 (0.1)**
2 hour post-breakfast: baseline	**10.89 (0.2)**	**11.82 (0.2)**
2 hour post-breakfast: change at week 30	**-3.56 (0.2)**	**-1.72 (0.2)**
Pre-lunch: baseline	**8.95 (0.2)**	**9.77 (0.2)**
Pre-lunch: change at week 30	**-2.23 (0.2)**	**-1.15 (0.2)**
2 hour post-lunch: baseline	**11.35 (0.2)**	**11.70 (0.2)**
2 hour post-lunch: change at week 30	**-2.74 (0.2)**	**-1.38 (0.2)**
Pre-dinner: baseline	**9.85 (0.2)**	**9.99 (0.2)**
Pre-dinner: change at week 30	**-2.25 (0.2)**	**-1.33 (0.2)**
2 hour post-dinner: baseline	**12.03 (0.3)**	**11.86 (0.3)**
2 hour post-dinner: change at week 30	**-3.87 (0.2)**	**-1.34 (0.3)**
0300: baseline	**8.95 (0.2)**	**9.20 (0.2)**
0300: change at week 30	**-2.27 (0.2)**	**-1.48 (0.2)**

No statistical analysis provided for Change in 7-point Self-monitored Blood Glucose (SMBG) Profile

6. Secondary: Change in Total Cholesterol [Time Frame: baseline and 30 weeks]

Measure Type	Secondary
Measure Title	Change in Total Cholesterol
Measure Description	Change in total cholesterol following 30 weeks of therapy (i.e., total cholesterol at week 30 minus total cholesterol at baseline)
Time Frame	baseline and 30 weeks

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set, Only patients with non-missing baseline value and at least one non-missing post-baseline value of the response variable were included in analysis

Reporting Groups

	Description
Exenatide Arm	Exenatide 5mcg twice daily for 4 weeks, followed by exenatide 10mcg twice daily for 26 weeks (with a background of titrated insulin glargine and other oral antidiabetic agents)
Placebo Arm	Placebo volume equivalent to the active volume injected in the exenatide arm (with a background of titrated insulin glargine and other oral antidiabetic agents)

Measured Values

	Exenatide Arm	**Placebo Arm**
Participants Analyzed	**110**	**98**
Change in Total Cholesterol [Units: mmol/L] Least Squares Mean (Standard Error)	**-0.16 (0.08)**	**-0.02 (0.09)**

Statistical Analysis 1 for Change in Total Cholesterol

Groups [1]	All groups

Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	ANCOVA
P Value [4]	0.203

[1] Additional details about the analysis, such as null hypothesis and power calculation:

No text entered.

[2] Details of power calculation, definition of non-inferiority margin, and other key parameters:

No text entered.

[3] Other relevant method information, such as adjustments or degrees of freedom:

No text entered.

[4] Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

No text entered.

7. Secondary: Change in Low Density Lipoprotein (LDL) Cholesterol [Time Frame: baseline and 30 weeks]

Measure Type	Secondary
Measure Title	Change in Low Density Lipoprotein (LDL) Cholesterol
Measure Description	Change in LDL cholesterol following 30 weeks of therapy (i.e., LDL cholesterol at week 30 minus LDL cholesterol at baseline)
Time Frame	baseline and 30 weeks

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set, Only patients with non-missing baseline value and at least one non-missing post-baseline value of the response variable were included in analysis

Reporting Groups

	Description
Exenatide Arm	Exenatide 5mcg twice daily for 4 weeks, followed by exenatide 10mcg twice daily for 26 weeks (with a background of titrated insulin glargine and other oral antidiabetic agents)
Placebo Arm	Placebo volume equivalent to the active volume injected in the exenatide arm (with a background of titrated insulin glargine and other oral antidiabetic agents)

Measured Values

	Exenatide Arm	Placebo Arm
Participants Analyzed	**102**	**97**
Change in Low Density Lipoprotein (LDL) Cholesterol [Units: mmol/L] Least Squares Mean (Standard Error)	**-0.19 (0.07)**	**-0.00 (0.07)**

Statistical Analysis 1 for Change in Low Density Lipoprotein (LDL) Cholesterol

Groups [1]	All groups
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	ANCOVA
P Value [4]	0.063

[1] Additional details about the analysis, such as null hypothesis and power calculation:

No text entered.

[2] Details of power calculation, definition of non-inferiority margin, and other key parameters:

No text entered.

[3] Other relevant method information, such as adjustments or degrees of freedom:

No text entered.

[4] Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

No text entered.

8. Secondary: Change in High Density Lipoprotein (HDL) Cholesterol [Time Frame: baseline and 30 weeks]

Measure Type	Secondary
Measure Title	Change in High Density Lipoprotein (HDL) Cholesterol
Measure Description	Change in HDL cholesterol following 30 weeks of therapy (i.e., HDL cholesterol at week 30 minus HDL cholesterol at baseline)
Time Frame	baseline and 30 weeks

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set, Only patients with non-missing baseline value and at least one non-missing post-baseline value of the response variable were included in analysis.

Reporting Groups

	Description
Exenatide Arm	Exenatide 5mcg twice daily for 4 weeks, followed by exenatide 10mcg twice daily for 26 weeks (with a background of titrated insulin glargine and other oral antidiabetic agents)
Placebo Arm	Placebo volume equivalent to the active volume injected in the exenatide arm (with a background of titrated insulin glargine and other oral antidiabetic agents)

Measured Values

	Exenatide Arm	**Placebo Arm**
Participants Analyzed	**110**	**98**
Change in High Density Lipoprotein (HDL) Cholesterol [Units: mmol/L] Least Squares Mean (Standard Error)	**0.01 (0.02)**	**0.00 (0.02)**

Statistical Analysis 1 for Change in High Density Lipoprotein (HDL) Cholesterol

Groups [1]	All groups
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	ANCOVA
P Value [4]	0.745

[1] Additional details about the analysis, such as null hypothesis and power calculation:

No text entered.

[2] Details of power calculation, definition of non-inferiority margin, and other key parameters:

No text entered.

[3] Other relevant method information, such as adjustments or degrees of freedom:

No text entered.

[4] Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

No text entered.

9. Secondary: Change in Triglycerides [Time Frame: baseline and 30 weeks]

Measure Type	Secondary
Measure Title	Change in Triglycerides
Measure Description	Change in triglycerides following 30 weeks of therapy (i.e., triglycerides at week 30 minus triglycerides at baseline)
Time Frame	baseline and 30 weeks

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

Full analysis set. Only patients with non-missing baseline value and at least one non-missing post-baseline value of the response variable were included in analysis

Reporting Groups

	Description
Exenatide Arm	Exenatide 5mcg twice daily for 4 weeks, followed by exenatide 10mcg twice daily for 26 weeks (with a background of titrated insulin glargine and other oral antidiabetic agents)
Placebo Arm	Placebo volume equivalent to the active volume injected in the exenatide arm (with a background of titrated insulin glargine and other oral antidiabetic agents)

Measured Values

	Exenatide Arm	Placebo Arm
Participants Analyzed	**110**	**98**
Change in Triglycerides [Units: mmol/L] Least Squares Mean (Standard Error)	**-0.02 (0.09)**	**-0.03 (0.09)**

Statistical Analysis 1 for Change in Triglycerides

Groups [1]	All groups
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	ANCOVA
P Value [4]	0.933

[1] Additional details about the analysis, such as null hypothesis and power calculation:

No text entered.

[2] Details of power calculation, definition of non-inferiority margin, and other key parameters:

No text entered.

[3] Other relevant method information, such as adjustments or degrees of freedom:

No text entered.

[4]

Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

No text entered.

10. Secondary: Change in Body Weight [Time Frame: baseline and 30 weeks]

Measure Type	Secondary
Measure Title	Change in Body Weight
Measure Description	Change in body weight following 30 weeks of therapy (i.e., body weight at week 30 minus body weight at baseline)
Time Frame	baseline and 30 weeks

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set, Only patients with non-missing baseline value and at least one non-missing post-baseline value of the response variable were included in analysis

Reporting Groups

	Description
Exenatide Arm	Exenatide 5mcg twice daily for 4 weeks, followed by exenatide 10mcg twice daily for 26 weeks (with a background of titrated insulin glargine and other oral antidiabetic agents)
Placebo Arm	Placebo volume equivalent to the active volume injected in the exenatide arm (with a background of titrated insulin glargine and other oral antidiabetic agents)

Measured Values

	Exenatide Arm	**Placebo Arm**
Participants Analyzed	**112**	**101**

Change in Body Weight [Units: Kg] Least Squares Mean (Standard Error)	**-1.78 (0.3)**	**0.96 (0.3)**

Statistical Analysis 1 for Change in Body Weight

Groups [1]	All groups
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	ANCOVA
P Value [4]	<0.001

[1] Additional details about the analysis, such as null hypothesis and power calculation:

No text entered.

[2] Details of power calculation, definition of non-inferiority margin, and other key parameters:

No text entered.

[3] Other relevant method information, such as adjustments or degrees of freedom:

No text entered.

[4] Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

No text entered.

11. Secondary: Change in Waist Circumference [Time Frame: baseline and 30 weeks]

Measure Type	Secondary
Measure Title	Change in Waist Circumference
Measure Description	Change in waist circumference following 30 weeks of therapy (i.e., waist circumference at week 30 minus waist circumference at baseline)
Time Frame	baseline and 30 weeks

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set, Only patients with non-missing baseline value and at least one non-missing post-baseline value of the response variable were included in analysis

Reporting Groups

	Description
Exenatide Arm	Exenatide 5mcg twice daily for 4 weeks, followed by exenatide 10mcg twice daily for 26 weeks (with a background of titrated insulin glargine and other oral antidiabetic agents)
Placebo Arm	Placebo volume equivalent to the active volume injected in the exenatide arm (with a background of titrated insulin glargine and other oral antidiabetic agents)

Measured Values

	Exenatide Arm	**Placebo Arm**
Participants Analyzed	**137**	**120**
Change in Waist Circumference [Units: Cm] Least Squares Mean (Standard Error)	**-1.08 (0.52)**	**-0.25 (0.55)**

Statistical Analysis 1 for Change in Waist Circumference

Groups [1]	All groups
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	ANCOVA
P Value [4]	0.226

[1] Additional details about the analysis, such as null hypothesis and power calculation:

No text entered.

[2] Details of power calculation, definition of non-inferiority margin, and other key parameters:

No text entered.

[3] Other relevant method information, such as adjustments or degrees of freedom:

No text entered.

[4] Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

No text entered.

12. Secondary: Change in Daily Insulin Dose [Time Frame: baseline and 30 weeks]

Measure Type	Secondary
Measure Title	Change in Daily Insulin Dose
Measure Description	Change in daily insulin dose following 30 weeks of therapy (i.e., daily insulin dose at week 30 minus daily insulin dose at baseline)
Time Frame	baseline and 30 weeks

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set, Only patients with non-missing baseline value and at least one non-missing post-baseline value of the response variable were included in analysis

Reporting Groups

	Description
Exenatide Arm	Exenatide 5mcg twice daily for 4 weeks, followed by exenatide 10mcg twice daily for 26 weeks (with a background of titrated insulin glargine and other oral antidiabetic agents)
Placebo Arm	Placebo volume equivalent to the active volume injected in the exenatide arm (with a background of titrated insulin glargine and other oral antidiabetic agents)

Measured Values

	Exenatide Arm	Placebo Arm
Participants Analyzed	**110**	**100**
Change in Daily Insulin Dose [Units: Insulin units (U)] Least Squares Mean (Standard Error)	**13.19 (2.02)**	**19.71 (2.11)**

Statistical Analysis 1 for Change in Daily Insulin Dose

Groups [1]	All groups
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	ANCOVA
P Value [4]	0.026

[1] Additional details about the analysis, such as null hypothesis and power calculation:

No text entered.

[2] Details of power calculation, definition of non-inferiority margin, and other key parameters:

No text entered.

[3] Other relevant method information, such as adjustments or degrees of freedom:

No text entered.

[4] Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

No text entered.

13. Secondary: Change in Daily Insulin Dose (on a Per Body Weight Basis) [Time Frame: baseline and 30 weeks]

Measure Type	Secondary
Measure Title	Change in Daily Insulin Dose (on a Per Body Weight Basis)
Measure Description	Change in daily insulin dose per kilogram (kg) following 30 weeks of therapy (i.e., daily insulin dose per kg at week 30 minus daily insulin dose per kg at baseline)

Time Frame	baseline and 30 weeks

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set, Only patients with non-missing baseline value and at least one non-missing post-baseline value of the response variable were included in analysis

Reporting Groups

	Description
Exenatide Arm	Exenatide 5mcg twice daily for 4 weeks, followed by exenatide 10mcg twice daily for 26 weeks (with a background of titrated insulin glargine and other oral antidiabetic agents)
Placebo Arm	Placebo volume equivalent to the active volume injected in the exenatide arm (with a background of titrated insulin glargine and other oral antidiabetic agents)

Measured Values

	Exenatide Arm	**Placebo Arm**
Participants Analyzed	**110**	**100**
Change in Daily Insulin Dose (on a Per Body Weight Basis) [Units: Insulin units per kg (U/kg)] Least Squares Mean (Standard Error)	**0.15 (0.02)**	**0.20 (0.02)**

Statistical Analysis 1 for Change in Daily Insulin Dose (on a Per Body Weight Basis)

Groups [1]	All groups
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	ANCOVA
P Value [4]	0.070

[1] Additional details about the analysis, such as null hypothesis and power calculation:

No text entered.

[2] Details of power calculation, definition of non-inferiority margin, and other key parameters:

No text entered.

[3] Other relevant method information, such as adjustments or degrees of freedom:

No text entered.

[4] Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

No text entered.

14. Secondary: Change in Systolic Blood Pressure (SBP) [Time Frame: baseline and 30 weeks]

Measure Type	Secondary
Measure Title	Change in Systolic Blood Pressure (SBP)
Measure Description	Change in SBP following 30 weeks of therapy (i.e., SBP at week 30 minus SBP at baseline)
Time Frame	baseline and 30 weeks

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set, Only patients with non-missing baseline value and at least one non-missing post-baseline value of the response variable were included in analysis

Reporting Groups

	Description
Exenatide Arm	Exenatide 5mcg twice daily for 4 weeks, followed by exenatide 10mcg twice daily for 26 weeks (with a background of titrated insulin glargine and other oral antidiabetic agents)
Placebo Arm	

	Placebo volume equivalent to the active volume injected in the exenatide arm (with a background of titrated insulin glargine and other oral antidiabetic agents)

Measured Values

	Exenatide Arm	Placebo Arm
Participants Analyzed	**112**	**101**
Change in Systolic Blood Pressure (SBP) [Units: mmHg] Least Squares Mean (Standard Error)	**-2.74 (1.2)**	**1.71 (1.3)**

Statistical Analysis 1 for Change in Systolic Blood Pressure (SBP)

Groups [1]	All groups
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	ANCOVA
P Value [4]	0.011

[1] Additional details about the analysis, such as null hypothesis and power calculation:

No text entered.

[2] Details of power calculation, definition of non-inferiority margin, and other key parameters:

No text entered.

[3] Other relevant method information, such as adjustments or degrees of freedom:

No text entered.

[4] Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

No text entered.

15. Secondary: Change in Diastolic Blood Pressure (DBP) [Time Frame: baseline and 30 weeks]

Measure Type	Secondary
Measure Title	Change in Diastolic Blood Pressure (DBP)
Measure Description	Change in DBP following 30 weeks of therapy (i.e., DBP at week 30 minus DBP at baseline)
Time Frame	baseline and 30 weeks

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set, Only patients with non-missing baseline value and at least one non-missing post-baseline value of the response variable were included in analysis

Reporting Groups

	Description
Exenatide Arm	Exenatide 5mcg twice daily for 4 weeks, followed by exenatide 10mcg twice daily for 26 weeks (with a background of titrated insulin glargine and other oral antidiabetic agents)
Placebo Arm	Placebo volume equivalent to the active volume injected in the exenatide arm (with a background of titrated insulin glargine and other oral antidiabetic agents)

Measured Values

	Exenatide Arm	**Placebo Arm**
Participants Analyzed	**112**	**101**
Change in Diastolic Blood Pressure (DBP) [Units: mmHg] Least Squares Mean (Standard Error)	**-1.73 (0.6)**	**1.69 (0.7)**

Statistical Analysis 1 for Change in Diastolic Blood Pressure (DBP)

Groups [1]	All groups

Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	ANCOVA
P Value [4]	<0.001

[1] Additional details about the analysis, such as null hypothesis and power calculation:

No text entered.

[2] Details of power calculation, definition of non-inferiority margin, and other key parameters:

No text entered.

[3] Other relevant method information, such as adjustments or degrees of freedom:

No text entered.

[4] Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

No text entered.

16. Secondary: Minor Hypoglycemia Rate Per Year [Time Frame: baseline and weeks 2, 4, 6, 8, 10, 14, 18, 22, 26, and 30]

Measure Type	Secondary
Measure Title	Minor Hypoglycemia Rate Per Year
Measure Description	Number of minor hypoglycemia events experienced per subject per year. Minor hypoglycemia was defined as any time a subject felt he or she was experiencing a sign or symptom associated with hypoglycemia that was either self-treated by the subject or resolved on its own and had a concurrent finger stick blood glucose <3.0 mmol/L (54 mg/dL).
Time Frame	baseline and weeks 2, 4, 6, 8, 10, 14, 18, 22, 26, and 30

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set

Reporting Groups

	Description
Exenatide Arm	Exenatide 5mcg twice daily for 4 weeks, followed by exenatide 10mcg twice daily for 26 weeks (with a background of titrated insulin glargine and other oral antidiabetic agents)
Placebo Arm	Placebo volume equivalent to the active volume injected in the exenatide arm (with a background of titrated insulin glargine and other oral antidiabetic agents)

Measured Values

	Exenatide Arm	Placebo Arm
Participants Analyzed	**137**	**122**
Minor Hypoglycemia Rate Per Year [Units: Events per subject per year] Mean (Standard Deviation)	**1.61 (5.94)**	**1.55 (4.79)**

Statistical Analysis 1 for Minor Hypoglycemia Rate Per Year

Groups [1]	All groups
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	Negative binomial regression model
P Value [4]	0.666

[1] Additional details about the analysis, such as null hypothesis and power calculation:

No text entered.

[2] Details of power calculation, definition of non-inferiority margin, and other key parameters:

No text entered.

[3] Other relevant method information, such as adjustments or degrees of freedom:

No text entered.

[4] Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

No text entered.

17. Secondary: Percentage of Subjects Experiencing Minor Hypoglycemia [Time Frame: baseline and weeks 2, 4, 6, 8, 10, 14, 18, 22, 26, and 30]

Measure Type	Secondary
Measure Title	Percentage of Subjects Experiencing Minor Hypoglycemia
Measure Description	Percentage of subjects in each arm experiencing at least one episode of minor hypoglycemia at any point during the study. Minor hypoglycemia was defined as any time a subject felt he or she was experiencing a sign or symptom associated with hypoglycemia that was either self-treated by the subject or resolved on its own and had a concurrent finger stick blood glucose <3.0 mmol/L (54 mg/dL).
Time Frame	baseline and weeks 2, 4, 6, 8, 10, 14, 18, 22, 26, and 30

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set

Reporting Groups

	Description
Exenatide Arm	Exenatide 5mcg twice daily for 4 weeks, followed by exenatide 10mcg twice daily for 26 weeks (with a background of titrated insulin glargine and other oral antidiabetic agents)
Placebo Arm	Placebo volume equivalent to the active volume injected in the exenatide arm (with a background of titrated insulin glargine and other oral antidiabetic agents)

Measured Values

	Exenatide Arm	**Placebo Arm**

Participants Analyzed	**137**	**122**
Percentage of Subjects Experiencing Minor Hypoglycemia [Units: Percentage]	**24.8**	**28.7**

Statistical Analysis 1 for Percentage of Subjects Experiencing Minor Hypoglycemia

Groups [1]	All groups
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	Fisher Exact
P Value [4]	0.486

[1] Additional details about the analysis, such as null hypothesis and power calculation:

No text entered.

[2] Details of power calculation, definition of non-inferiority margin, and other key parameters:

No text entered.

[3] Other relevant method information, such as adjustments or degrees of freedom:

No text entered.

[4] Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

No text entered.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
Exenatide Arm	

	Exenatide 5mcg twice daily for 4 weeks, followed by exenatide 10mcg twice daily for 26 weeks (with a background of titrated insulin glargine and other oral antidiabetic agents)
Placebo Arm	Placebo volume equivalent to the active volume injected in the exenatide arm (with a background of titrated insulin glargine and other oral antidiabetic agents)

Serious Adverse Events

	Exenatide Arm	Placebo Arm
Total, Serious Adverse Events		
# participants affected / at risk	**8/137 (5.84%)**	**11/122 (9.02%)**
Cardiac disorders		
Angina unstable [*1]		
# participants affected / at risk	**0/137 (0.00%)**	**1/122 (0.82%)**
Coronary artery occlusion [*1]		
# participants affected / at risk	**1/137 (0.73%)**	**0/122 (0.00%)**
Myocardial infarction [*1]		
# participants affected / at risk	**0/137 (0.00%)**	**1/122 (0.82%)**
Palpitations [*1]		
# participants affected / at risk	**0/137 (0.00%)**	**1/122 (0.82%)**
Transient ischemic attack [*1]		
# participants affected / at risk	**0/137 (0.00%)**	**1/122 (0.82%)**
Gastrointestinal disorders		
Small intestine obstruction [*1]		
# participants affected / at risk	**0/137 (0.00%)**	**1/122 (0.82%)**
General disorders		
Chest pain [*1]		
# participants affected / at risk	**1/137 (0.73%)**	**1/122 (0.82%)**
Infections and infestations		
Herpes zoster [*1]		
# participants affected / at risk	**1/137 (0.73%)**	**0/122 (0.00%)**

Sepsis [*1]		
# participants affected / at risk	**0/137 (0.00%)**	**1/122 (0.82%)**
Staphylococcal infection [*1]		
# participants affected / at risk	**1/137 (0.73%)**	**0/122 (0.00%)**
Injury, poisoning and procedural complications		
Accidental overdose [*1]		
# participants affected / at risk	**1/137 (0.73%)**	**0/122 (0.00%)**
Ankle fracture [*1]		
# participants affected / at risk	**0/137 (0.00%)**	**1/122 (0.82%)**
Eye penetration [*1]		
# participants affected / at risk	**1/137 (0.73%)**	**0/122 (0.00%)**
Fall [*1]		
# participants affected / at risk	**1/137 (0.73%)**	**0/122 (0.00%)**
Metabolism and nutrition disorders		
Hypoglycemia [*1]		
# participants affected / at risk	**0/137 (0.00%)**	**1/122 (0.82%)**
Musculoskeletal and connective tissue disorders		
Osteoarthritis [*1]		
# participants affected / at risk	**2/137 (1.46%)**	**0/122 (0.00%)**
Psychiatric disorders		
Suicide attempt [*1]		
# participants affected / at risk	**0/137 (0.00%)**	**1/122 (0.82%)**
Renal and urinary disorders		
Cystitis [*1]		
# participants affected / at risk	**0/137 (0.00%)**	**1/122 (0.82%)**
Respiratory, thoracic and mediastinal disorders		
Dyspnea [*1]		
# participants affected / at risk	**1/137 (0.73%)**	**0/122 (0.00%)**
Pulmonary embolism [*1]		
# participants affected / at risk	**0/137 (0.00%)**	**1/122 (0.82%)**
Skin and subcutaneous tissue disorders		

Uticaria * 1		
# participants affected / at risk	**0/137 (0.00%)**	**1/122 (0.82%)**

* Events were collected by non-systematic assessment

1 Term from vocabulary, MedDRA 12.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Exenatide Arm	Exenatide 5mcg twice daily for 4 weeks, followed by exenatide 10mcg twice daily for 26 weeks (with a background of titrated insulin glargine and other oral antidiabetic agents)
Placebo Arm	Placebo volume equivalent to the active volume injected in the exenatide arm (with a background of titrated insulin glargine and other oral antidiabetic agents)

Other Adverse Events

	Exenatide Arm	**Placebo Arm**
Total, Other (not including serious) Adverse Events		
# participants affected / at risk	**109/138 (78.99%)**	**66/123 (53.66%)**
Gastrointestinal disorders		

Nausea [*1]		
# participants affected / at risk	**56/138 (40.58%)**	**10/123 (8.13%)**
Diarrhea [*1]		
# participants affected / at risk	**25/138 (18.12%)**	**10/123 (8.13%)**
Vomiting [*1]		
# participants affected / at risk	**25/138 (18.12%)**	**5/123 (4.07%)**
Constipation [*1]		
# participants affected / at risk	**14/138 (10.14%)**	**2/123 (1.63%)**
Dyspepsia [*1]		
# participants affected / at risk	**9/138 (6.52%)**	**2/123 (1.63%)**
General disorders		
Asthenia [*1]		
# participants affected / at risk	**7/138 (5.07%)**	**1/123 (0.81%)**
Infections and infestations		
Nasopharyngitis [*1]		
# participants affected / at risk	**8/138 (5.80%)**	**6/123 (4.88%)**
Musculoskeletal and connective tissue disorders		
Back Pain [*1]		
# participants affected / at risk	**9/138 (6.52%)**	**2/123 (1.63%)**
Nervous system disorders		
Headache [*1]		
# participants affected / at risk	**19/138 (13.77%)**	**5/123 (4.07%)**
Dizziness [*1]		
# participants affected / at risk	**6/138 (4.35%)**	**7/123 (5.69%)**
Respiratory, thoracic and mediastinal disorders		
Upper Respiratory Tract Infection [*1]		
# participants affected / at risk	**11/138 (7.97%)**	**9/123 (7.32%)**
Cough [*1]		
# participants affected / at risk	**7/138 (5.07%)**	**7/123 (5.69%)**

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA 12.0

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☑ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

Results Point of Contact:

Name/Title: Peter Ohman, Medical Science Director
Organization: AstraZeneca
e-mail: ClinicalTrialTransparency@astrazeneca.com

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Buse JB, Han J, Miller S, MacConell L, Pencek R, Wintle M. Addition of exenatide BID to insulin glargine: a post-hoc analysis of the effect on glycemia and weight across a range of insulin titration. Curr Med Res Opin. 2014 Jul;30(7):1209-18. doi: 10.1185/03007995.2014.896329. Epub 2014 Mar 18.

Zinman B, Philis-Tsimikas A, Cariou B, Handelsman Y, Rodbard HW, Johansen T, Endahl L, Mathieu C; NN1250-3579 (BEGIN Once Long) Trial Investigators. Insulin degludec versus insulin glargine in insulin-naive patients with type 2 diabetes: a 1-year, randomized, treat-to-target trial (BEGIN Once Long). Diabetes Care. 2012 Dec;35(12):2464-71. doi: 10.2337/dc12-1205. Epub 2012 Oct 5.

Pencek R, Blickensderfer A, Li Y, Brunell SC, Anderson PW. Exenatide twice daily: analysis of effectiveness and safety data stratified by age, sex, race, duration of diabetes, and body mass index. Postgrad Med. 2012 Jul;124(4):21-32. doi: 10.3810/pgm.2012.07.2567.

Rosenstock J, Shenouda SK, Bergenstal RM, Buse JB, Glass LC, Heilmann CR, Kwan AY, MacConell LA, Hoogwerf BJ. Baseline factors associated with glycemic control and weight loss when exenatide twice daily is added to optimized insulin glargine in patients with type 2 diabetes. Diabetes Care. 2012 May;35(5):955-8. doi: 10.2337/dc11-1434. Epub 2012 Mar 19.

Buse JB, Bergenstal RM, Glass LC, Heilmann CR, Lewis MS, Kwan AY, Hoogwerf BJ, Rosenstock J. Use of twice-daily exenatide in Basal insulin-treated patients with type 2 diabetes: a randomized, controlled trial. Ann Intern Med. 2011 Jan 18;154(2):103-12. doi: 10.7326/0003-4819-154-2-201101180-00300. Epub 2010 Dec 6.

Responsible Party:	AstraZeneca
ClinicalTrials.gov Identifier:	NCT00765817 History of Changes
Other Study ID Numbers:	H8O-US-**GWCO**
First Submitted:	October 1, 2008
First Posted:	October 3, 2008
Results First Submitted:	January 4, 2011
Results First Posted:	January 26, 2011

Last Update Posted: October 24, 2016