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Trial record **1 of 1** for: H8O-CR-GWDK

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A Comparison of Adding Exenatide With Switching to Exenatide in Patients With Type 2 Diabetes Experiencing Inadequate Glycemic Control With Sitagliptin Plus Metformin

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT00870194

Recruitment Status: Completed
First Posted: March 27, 2009
Results First Posted: June 17, 2011
Last Update Posted: April 9, 2015

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 Mellitus
Interventions:	Drug: exenatide and sitagliptin Drug: exenatide and placebo

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
No text entered.

Reporting Groups

	Description
Exenatide + Placebo	Exenatide-subcutaneous injection, 5mcg (4 weeks) followed by 10mcg (16 weeks), twice a day; Placebo-tablet orally once a day.
Exenatide + Sitagliptin	Exenatide-subcutaneous injection, 5mcg (4 weeks) followed by 10mcg (16 weeks), twice a day; Sitagliptin-100mg tablet orally once a day.

Participant Flow: Overall Study

	Exenatide + Placebo	**Exenatide + Sitagliptin**

STARTED	**127**	**128**
Per Protocol Set	**97**	**111**
COMPLETED	**101**	**114**
NOT COMPLETED	**26**	**14**
Adverse Event	**10**	**5**
Lack of Efficacy	**0**	**1**
Lost to Follow-up	**2**	**0**
Physician Decision	**3**	**1**
Protocol Violation	**3**	**3**
Entry Criteria Not Met	**1**	**2**
Subject Decision	**7**	**2**

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.
No text entered.

Reporting Groups

	Description
Exenatide + Placebo	Exenatide-subcutaneous injection, 5mcg (4 weeks) followed by 10mcg (16 weeks), twice a day; Placebo-tablet orally once a day.
Exenatide + Sitagliptin	Exenatide-subcutaneous injection, 5mcg (4 weeks) followed by 10mcg (16 weeks), twice a day; Sitagliptin-100mg tablet orally once a day.
Total	Total of all reporting groups

Baseline Measures

	Exenatide + Placebo	Exenatide + Sitagliptin	Total
Overall Participants Analyzed [Units: Participants]	**97**	**111**	**208**
Age [Units: Participants]			
<=18 years	**0**	**0**	**0**
Between 18 and 65 years	**81**	**97**	**178**
>=65 years	**16**	**14**	**30**
Age [Units: Years] Mean (Standard Deviation)	**54.8 (10.97)**	**54.6 (9.66)**	**54.7 (10.27)**
Gender [Units: Participants]			
Female	**46**	**58**	**104**
Male	**51**	**53**	**104**

Outcome Measures

Hide All Outcome Measures

1. Primary: Change in HbA1c (Percent) [Time Frame: Baseline to 20 Weeks]

Measure Type	Primary
Measure Title	Change in HbA1c (Percent)
Measure Description	Change in HbA1c from baseline to endpoint (Week 20); difference of base percent values [X% - Y%]
Time Frame	Baseline to 20 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.
Per Protocol Set: the set of data generated by the subset of patients who sufficiently complied with the protocol to ensure that these data would be likely to exhibit the effects of treatment, according to the underlying scientific model.

Reporting Groups

	Description
Exenatide + Placebo	Exenatide-subcutaneous injection, 5mcg (4 weeks) followed by 10mcg (16 weeks), twice a day; Placebo-tablet orally once a day.
Exenatide + Sitagliptin	Exenatide-subcutaneous injection, 5mcg (4 weeks) followed by 10mcg (16 weeks), twice a day; Sitagliptin-100mg tablet orally once a day.

Measured Values

	Exenatide + Placebo	**Exenatide + Sitagliptin**
Participants Analyzed	**97**	**111**
Change in HbA1c (Percent) [Units: Percent HbA1c] Least Squares Mean (Standard Error)	**-0.38 (0.09)**	**-0.68 (0.08)**

Statistical Analysis 1 for Change in HbA1c (Percent)

Groups [1]	All groups
Statistical Test Type [2]	Non-Inferiority or Equivalence
Statistical Method [3]	Mixed Model Repeated Measures
P Value [4]	.012

[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:

Non-Inferiority Margin of 0.4%

[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.

Statistical Analysis 2 for Change in HbA1c (Percent)

Groups [1]	All groups
Statistical Test Type [2]	Non-Inferiority or Equivalence
Statistical Method [3]	Mixed Model Repeated Measures
P Value [4]	.012
Least Square Mean Difference [5]	0.30
95% Confidence Interval	0.07 to 0.53
Standard Error of the mean	(0.12)

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

Power calculation: 80% assuming 200 patients (100 in each arm), no true difference and 1.0% standard deviation.

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

Non-inferiority margin of 0.4%

[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] Other relevant estimation information:

Standard Error of the Least Square Mean

2. Secondary:

Percentage of Patients Achieving HbA1c <=7.0% [Time Frame: Baseline to 20 Weeks]

Measure Type	Secondary
Measure Title	Percentage of Patients Achieving HbA1c <=7.0%
Measure Description	Percentage of patients whose baseline HbA1c was > 7.0% achieving HbA1c <=7.0% at endpoint (Week 20)
Time Frame	Baseline to 20 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.
Patients in the Per Protocol Set whose baseline HbA1c was > 7.0%; Last Observation Carried Forward.Per Protocol Set: the set of data generated by the subset of patients who sufficiently complied with the protocol to ensure that these data would be likely to exhibit the effects of treatment, according to the underlying scientific model.

Reporting Groups

	Description
Exenatide + Placebo	Exenatide-subcutaneous injection, 5mcg (4 weeks) followed by 10mcg (16 weeks), twice a day; Placebo-tablet orally once a day.
Exenatide + Sitagliptin	Exenatide-subcutaneous injection, 5mcg (4 weeks) followed by 10mcg (16 weeks), twice a day; Sitagliptin-100mg tablet orally once a day.

Measured Values

	Exenatide + Placebo	**Exenatide + Sitagliptin**
Participants Analyzed	**88**	**106**
Percentage of Patients Achieving HbA1c <=7.0% [Units: Percentage]	**29.5**	**44.3**

Statistical Analysis 1 for Percentage of Patients Achieving HbA1c <=7.0%

Groups [1]	All groups
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	Fisher`s Exact Test
P Value [4]	.038

[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 <7.0% [Time Frame: Baseline to 20 Weeks]

Measure Type	Secondary
Measure Title	Percentage of Patients Achieving HbA1c <7.0%
Measure Description	Percentage of patients whose baseline HbA1c was >=7.0% achieving HbA1c <7.0% at endpoint (Week 20)
Time Frame	Baseline to 20 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.

Patients in the Per Protocol Set whose baseline HbA1c was >= 7.0%; Last Observation Carried Forward. Per Protocol Set: the set of data generated by the subset of patients who sufficiently complied with the protocol to ensure that these data would be likely to exhibit the effects of treatment, according to the underlying scientific model.

Reporting Groups

	Description
Exenatide + Placebo	Exenatide-subcutaneous injection, 5mcg (4 weeks) followed by 10mcg (16 weeks), twice a day; Placebo-tablet orally once a day.
Exenatide + Sitagliptin	Exenatide-subcutaneous injection, 5mcg (4 weeks) followed by 10mcg (16 weeks), twice a day; Sitagliptin-100mg tablet orally once a day.

Measured Values

	Exenatide + Placebo	**Exenatide + Sitagliptin**
Participants Analyzed	**94**	**108**
Percentage of Patients Achieving HbA1c <7.0% [Units: Percentage]	**26.6**	**41.7**

Statistical Analysis 1 for Percentage of Patients Achieving HbA1c <7.0%

Groups [1]	All groups
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	Fisher`s Exact Test
P Value [4]	.027

[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: Percentage of Patients Achieving HbA1c <=6.5% [Time Frame: Baseline to 20 Weeks]

Measure Type	Secondary
Measure Title	Percentage of Patients Achieving HbA1c <=6.5%
Measure Description	Percentage of patients whose baseline HbA1c was > 6.5% achieving HbA1c <=6.5% at endpoint (Week 20)
Time Frame	Baseline to 20 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.
Patients in the Per Protocol Set whose baseline HbA1c was > 6.5%; Last Observation Carried Forward. Per Protocol Set: the set of data generated by the subset of patients who sufficiently complied with the protocol to ensure that these data would be likely to exhibit the effects of treatment, according to the underlying scientific model.

Reporting Groups

	Description
Exenatide + Placebo	Exenatide-subcutaneous injection, 5mcg (4 weeks) followed by 10mcg (16 weeks), twice a day; Placebo-tablet orally once a day.
Exenatide + Sitagliptin	Exenatide-subcutaneous injection, 5mcg (4 weeks) followed by 10mcg (16 weeks), twice a day; Sitagliptin-100mg tablet orally once a day.

Measured Values

	Exenatide + Placebo	**Exenatide + Sitagliptin**

Participants Analyzed	**97**	**111**
Percentage of Patients Achieving HbA1c <=6.5% [Units: Percentage]	**16.5**	**20.7**

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]	Fisher`s Exact Test
P Value [4]	.480

[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 FSG (mmol/L) [Time Frame: Baseline to 20 Weeks]

Measure Type	Secondary
Measure Title	Change in FSG (mmol/L)
Measure Description	Change in fasting serum glucose (FSG) from baseline to endpoint (Week 20)
Time Frame	Baseline to 20 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.
Per Protocol Set: the set of data generated by the subset of patients who sufficiently complied with the protocol to ensure that these data would be likely to exhibit the effects of treatment, according to the underlying scientific model.

Reporting Groups

	Description
Exenatide + Placebo	Exenatide-subcutaneous injection, 5mcg (4 weeks) followed by 10mcg (16 weeks), twice a day; Placebo-tablet orally once a day.
Exenatide + Sitagliptin	Exenatide-subcutaneous injection, 5mcg (4 weeks) followed by 10mcg (16 weeks), twice a day; Sitagliptin-100mg tablet orally once a day.

Measured Values

	Exenatide + Placebo	**Exenatide + Sitagliptin**
Participants Analyzed	**93**	**106**
Change in FSG (mmol/L) [Units: mmol/L] Least Squares Mean (Standard Error)	**0.06 (0.23)**	**-0.55 (0.21)**

Statistical Analysis 1 for Change in FSG (mmol/L)

Groups [1]	All groups
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	ANCOVA
P Value [4]	.038

[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.

6. Secondary: Change in Body Weight (kg) [Time Frame: Baseline to 20 Weeks]

Measure Type	Secondary
Measure Title	Change in Body Weight (kg)
Measure Description	Change in body weight from baseline to endpoint (Week 20)
Time Frame	Baseline to 20 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.
Per Protocol Set: the set of data generated by the subset of patients who sufficiently complied with the protocol to ensure that these data would be likely to exhibit the effects of treatment, according to the underlying scientific model.

Reporting Groups

	Description
Exenatide + Placebo	Exenatide-subcutaneous injection, 5mcg (4 weeks) followed by 10mcg (16 weeks), twice a day; Placebo-tablet orally once a day.
Exenatide + Sitagliptin	Exenatide-subcutaneous injection, 5mcg (4 weeks) followed by 10mcg (16 weeks), twice a day; Sitagliptin-100mg tablet orally once a day.

Measured Values

	Exenatide + Placebo	Exenatide + Sitagliptin
Participants Analyzed	**97**	**111**
Change in Body Weight (kg) [Units: Kg] Least Squares Mean (Standard Error)	**-2.58 (0.25)**	**-2.20 (0.24)**

Statistical Analysis 1 for Change in Body Weight (kg)

Groups [1]	All groups
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	Mixed Model Repeated Measures
P Value [4]	.266

[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 Waist Circumference (cm) [Time Frame: Baseline to 20 Weeks]

Measure Type	Secondary
Measure Title	Change in Waist Circumference (cm)
Measure Description	Change in waist circumference from baseline to endpoint (Week 20)
Time Frame	Baseline to 20 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.
Per Protocol Set: the set of data generated by the subset of patients who sufficiently complied with the protocol to ensure that these data would be likely to exhibit the effects of treatment, according to the underlying scientific model.

Reporting Groups

	Description
Exenatide + Placebo	Exenatide-subcutaneous injection, 5mcg (4 weeks) followed by 10mcg (16 weeks), twice a day; Placebo-tablet orally once a day.
Exenatide + Sitagliptin	Exenatide-subcutaneous injection, 5mcg (4 weeks) followed by 10mcg (16 weeks), twice a day; Sitagliptin-100mg tablet orally once a day.

Measured Values

	Exenatide + Placebo	**Exenatide + Sitagliptin**
Participants Analyzed	**96**	**111**
Change in Waist Circumference (cm) [Units: Cm] Least Squares Mean (Standard Error)	**-3.25 (0.40)**	**-2.36 (0.37)**

Statistical Analysis 1 for Change in Waist Circumference (cm)

Groups [1]	All groups
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	Mixed Model Repeated Measures
P Value [4]	.095

[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: Waist-to-Hip Ratio [Time Frame: Baseline to 20 Weeks]

Measure Type	Secondary
Measure Title	Waist-to-Hip Ratio
Measure Description	Change in waist-to-hip ratio from baseline to endpoint (Week20)
Time Frame	Baseline to 20 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.
Per Protocol Set: the set of data generated by the subset of patients who sufficiently complied with the protocol to ensure that these data would be likely to exhibit the effects of treatment, according to the underlying scientific model.

Reporting Groups

	Description
Exenatide + Placebo	Exenatide-subcutaneous injection, 5mcg (4 weeks) followed by 10mcg (16 weeks), twice a day; Placebo-tablet orally once a day.
Exenatide + Sitagliptin	Exenatide-subcutaneous injection, 5mcg (4 weeks) followed by 10mcg (16 weeks), twice a day; Sitagliptin-100mg tablet orally once a day.

Measured Values

	Exenatide + Placebo	Exenatide + Sitagliptin
Participants Analyzed	**96**	**111**
Waist-to-Hip Ratio [Units: Ratio] Least Squares Mean (Standard Error)	**-0.01 (0.00)**	**-0.00 (0.00)**

Statistical Analysis 1 for Waist-to-Hip Ratio

Groups [1]	All groups
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	Mixed Model Repeated Measures
P Value [4]	.567

[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: SMBG (mmol/L) [Time Frame: Baseline to 20 Weeks]

Measure Type	Secondary
Measure Title	SMBG (mmol/L)
Measure Description	7 point Self Monitored Blood Glucose Profiles - daily mean value (Week 20)
Time Frame	Baseline to 20 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.
Per Protocol Set: the set of data generated by the subset of patients who sufficiently complied with the protocol to ensure that these data would be likely to exhibit the effects of treatment, according to the underlying scientific model.

Reporting Groups

	Description
Exenatide + Placebo	Exenatide-subcutaneous injection, 5mcg (4 weeks) followed by 10mcg (16 weeks), twice a day; Placebo-tablet orally once a day.
Exenatide + Sitagliptin	Exenatide-subcutaneous injection, 5mcg (4 weeks) followed by 10mcg (16 weeks), twice a day; Sitagliptin-100mg tablet orally once a day.

Measured Values

	Exenatide + Placebo	**Exenatide + Sitagliptin**
Participants Analyzed	**50**	**71**
SMBG (mmol/L) [Units: mmol/L] Least Squares Mean (Standard Error)	**8.57 (0.26)**	**8.16 (0.22)**

Statistical Analysis 1 for SMBG (mmol/L)

Groups [1]	All groups
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	Mixed Model Repeated Measures
P Value [4]	.207

[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 Triglycerides (mmol/L) [Time Frame: Baseline to 20 Weeks]

Measure Type	Secondary
Measure Title	Change in Triglycerides (mmol/L)
Measure Description	Change in triglycerides from baseline to endpoint (Week 20)
Time Frame	Baseline to 20 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.
Per Protocol Set: the set of data generated by the subset of patients who sufficiently complied with the protocol to ensure that these data would be likely to exhibit the effects of treatment, according to the underlying scientific model.

Reporting Groups

	Description
Exenatide + Placebo	Exenatide-subcutaneous injection, 5mcg (4 weeks) followed by 10mcg (16 weeks), twice a day; Placebo-tablet orally once a day.
Exenatide + Sitagliptin	Exenatide-subcutaneous injection, 5mcg (4 weeks) followed by 10mcg (16 weeks), twice a day; Sitagliptin-100mg tablet orally once a day.

Measured Values

	Exenatide + Placebo	Exenatide + Sitagliptin
Participants Analyzed	**96**	**109**
Change in Triglycerides (mmol/L) [Units: mmol/L] Least Squares Mean (Standard Error)	**0.17 (0.10)**	**-0.07 (0.09)**

Statistical Analysis 1 for Change in Triglycerides (mmol/L)

Groups [1]	All groups
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	ANCOVA
P Value [4]	.055

[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 HDL (mmol/L) [Time Frame: Baseline to 20 Weeks]

Measure Type	Secondary
Measure Title	Change in HDL (mmol/L)
Measure Description	Change in high-density lipoprotein (HDL) cholesterol from baseline to endpoint (Week 20)
Time Frame	Baseline to 20 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.
Per Protocol Set: the set of data generated by the subset of patients who sufficiently complied with the protocol to ensure that these data would be likely to exhibit the effects of treatment, according to the underlying scientific model.

Reporting Groups

	Description
Exenatide + Placebo	Exenatide-subcutaneous injection, 5mcg (4 weeks) followed by 10mcg (16 weeks), twice a day; Placebo-tablet orally once a day.
Exenatide + Sitagliptin	Exenatide-subcutaneous injection, 5mcg (4 weeks) followed by 10mcg (16 weeks), twice a day; Sitagliptin-100mg tablet orally once a day.

Measured Values

	Exenatide + Placebo	**Exenatide + Sitagliptin**
Participants Analyzed	**96**	**109**
Change in HDL (mmol/L) [Units: mmol/L] Least Squares Mean (Standard Error)	**-0.03 (0.02)**	**-0.01 (0.02)**

Statistical Analysis 1 for Change in HDL (mmol/L)

Groups [1]	All groups
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	ANCOVA
P Value [4]	.269

[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 LDL (mmol/L) [Time Frame: Baseline to 20 Weeks]

Measure Type	Secondary
Measure Title	Change in LDL (mmol/L)
Measure Description	Change in low-density lipoprotein (LDL) cholesterol from baseline to endpoint (Week 20)
Time Frame	Baseline to 20 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.
Per Protocol Set: the set of data generated by the subset of patients who sufficiently complied with the protocol to ensure that these data would be likely to exhibit the effects of treatment, according to the underlying scientific model.

Reporting Groups

	Description
Exenatide + Placebo	Exenatide-subcutaneous injection, 5mcg (4 weeks) followed by 10mcg (16 weeks), twice a day; Placebo-tablet orally once a day.
Exenatide + Sitagliptin	Exenatide-subcutaneous injection, 5mcg (4 weeks) followed by 10mcg (16 weeks), twice a day; Sitagliptin-100mg tablet orally once a day.

Measured Values

	Exenatide + Placebo	Exenatide + Sitagliptin
Participants Analyzed	**90**	**98**
Change in LDL (mmol/L) [Units: mmol/L] Least Squares Mean (Standard Error)	**0.06 (0.06)**	**0.10 (0.06)**

Statistical Analysis 1 for Change in LDL (mmol/L)

Groups [1]	All groups
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	ANCOVA
P Value [4]	.622

[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 Total Cholesterol (mmol/L) [Time Frame: Baseline to 20 Weeks]

Measure Type	Secondary
Measure Title	Change in Total Cholesterol (mmol/L)

Measure Description	Change in total cholesterol from baseline to endpoint (Week 20)
Time Frame	Baseline to 20 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.
Per Protocol Set: the set of data generated by the subset of patients who sufficiently complied with the protocol to ensure that these data would be likely to exhibit the effects of treatment, according to the underlying scientific model.

Reporting Groups

	Description
Exenatide + Placebo	Exenatide-subcutaneous injection, 5mcg (4 weeks) followed by 10mcg (16 weeks), twice a day; Placebo-tablet orally once a day.
Exenatide + Sitagliptin	Exenatide-subcutaneous injection, 5mcg (4 weeks) followed by 10mcg (16 weeks), twice a day; Sitagliptin-100mg tablet orally once a day.

Measured Values

	Exenatide + Placebo	**Exenatide + Sitagliptin**
Participants Analyzed	**96**	**109**
Change in Total Cholesterol (mmol/L) [Units: mmol/L] Least Squares Mean (Standard Error)	**0.09 (0.07)**	**0.08 (0.07)**

Statistical Analysis 1 for Change in Total Cholesterol (mmol/L)

Groups [1]	All groups
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	ANCOVA
P Value [4]	.888

[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: Incidence of Hypoglycemia (Overall) [Time Frame: Baseline to 20 Weeks]

Measure Type	Secondary
Measure Title	Incidence of Hypoglycemia (Overall)
Measure Description	Incidence of hypoglycemic episodes experienced overall during the study
Time Frame	Baseline to 20 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.
As Treated Patients; Hypoglycemia defined as: patient experiencing a sign or symptom associated with hypoglycemia that is either self-treated or resolves on its own; not confirmed with blood glucose values.

Reporting Groups

	Description
Exenatide + Placebo	Exenatide-subcutaneous injection, 5mcg (4 weeks) followed by 10mcg (16 weeks), twice a day; Placebo-tablet orally once a day.
Exenatide + Sitagliptin	

	Exenatide-subcutaneous injection, 5mcg (4 weeks) followed by 10mcg (16 weeks), twice a day; Sitagliptin-100mg tablet orally once a day.

Measured Values

	Exenatide + Placebo	Exenatide + Sitagliptin
Participants Analyzed	**127**	**128**
Incidence of Hypoglycemia (Overall) [Units: Participants]	**5**	**10**

Statistical Analysis 1 for Incidence of Hypoglycemia (Overall)

Groups [1]	All groups
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	Fisher`s Exact Test
P Value [4]	.287

[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: Incidence of Severe Hypoglycemia(Overall) [Time Frame: Baseline to 20 Weeks]

Measure Type	Secondary
Measure Title	Incidence of Severe Hypoglycemia(Overall)

Measure Description	Incidence of severe hypoglycemia experienced overall during the study
Time Frame	Baseline to 20 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.
As Treated Patients; Severe hypo:symptoms consistent with hypoglycemia resulting in loss of consciousness or seizure with prompt recovery in response to administration of glucagon or glucose;or documented hypoglycemia (BG< 3.0 mmol/L [54/mg/dL]) requiring the assistance of another person because of severe impairment in consciousness or behavior

Reporting Groups

	Description
Exenatide + Placebo	Exenatide-subcutaneous injection, 5mcg (4 weeks) followed by 10mcg (16 weeks), twice a day; Placebo-tablet orally once a day.
Exenatide + Sitagliptin	Exenatide-subcutaneous injection, 5mcg (4 weeks) followed by 10mcg (16 weeks), twice a day; Sitagliptin-100mg tablet orally once a day.

Measured Values

	Exenatide + Placebo	**Exenatide + Sitagliptin**
Participants Analyzed	**127**	**128**
Incidence of Severe Hypoglycemia(Overall) [Units: Participants]	**1**	**0**

Statistical Analysis 1 for Incidence of Severe Hypoglycemia(Overall)

Groups [1]	All groups
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	Fisher`s Exact Test
P Value [4]	.498

[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: Incidence of Nocturnal Hypoglycemia (Overall) [Time Frame: Baseline to 20 Weeks]

Measure Type	Secondary
Measure Title	Incidence of Nocturnal Hypoglycemia (Overall)
Measure Description	Incidence of nocturnal hypoglycemia experienced overall during the study
Time Frame	Baseline to 20 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.
As Treated Patients

Reporting Groups

	Description
Exenatide + Placebo	Exenatide-subcutaneous injection, 5mcg (4 weeks) followed by 10mcg (16 weeks), twice a day; Placebo-tablet orally once a day.
Exenatide + Sitagliptin	Exenatide-subcutaneous injection, 5mcg (4 weeks) followed by 10mcg (16 weeks), twice a day; Sitagliptin-100mg tablet orally once a day.

Measured Values

	Exenatide + Placebo	Exenatide + Sitagliptin
Participants Analyzed	**127**	**128**
Incidence of Nocturnal Hypoglycemia (Overall) [Units: Participants]	**0**	**3**

Statistical Analysis 1 for Incidence of Nocturnal Hypoglycemia (Overall)

Groups [1]	All groups
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	Fisher`s Exact Test
P Value [4]	.247

[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: Incidence of Confirmed Hypoglycemia(Overall) [Time Frame: Baseline to 20 Weeks]

Measure Type	Secondary
Measure Title	Incidence of Confirmed Hypoglycemia(Overall)
Measure Description	

	Incidence of confirmed hypoglycemia experienced overall during the study
Time Frame	Baseline to 20 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.
As Treated Patients; Hypoglycemia defined as: patient experiencing a sign or symptom associated with hypoglycemia that is either self-treated or resolves on its own; has a concurrent fingerstick blood glucose <3.0 mmol/L (54 mg/dL).

Reporting Groups

	Description
Exenatide + Placebo	Exenatide-subcutaneous injection, 5mcg (4 weeks) followed by 10mcg (16 weeks), twice a day; Placebo-tablet orally once a day.
Exenatide + Sitagliptin	Exenatide-subcutaneous injection, 5mcg (4 weeks) followed by 10mcg (16 weeks), twice a day; Sitagliptin-100mg tablet orally once a day.

Measured Values

	Exenatide + Placebo	**Exenatide + Sitagliptin**
Participants Analyzed	**127**	**128**
Incidence of Confirmed Hypoglycemia(Overall) [Units: Participants]	**1**	**2**

Statistical Analysis 1 for Incidence of Confirmed Hypoglycemia(Overall)

Groups [1]	All groups
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	Fisher`s Exact Test
P Value [4]	1.00

[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 + Placebo	Exenatide-subcutaneous injection, 5mcg (4 weeks) followed by 10mcg (16 weeks), twice a day; Placebo-tablet orally once a day.
Exenatide + Sitagliptin	Exenatide-subcutaneous injection, 5mcg (4 weeks) followed by 10mcg (16 weeks), twice a day; Sitagliptin-100mg tablet orally once a day.

Serious Adverse Events

	Exenatide + Placebo	**Exenatide + Sitagliptin**
Total, Serious Adverse Events		
# participants affected / at risk	**4/127 (3.15%)**	**6/128 (4.69%)**
Cardiac disorders		

Angina unstable [*1]		
# participants affected / at risk	**0/127 (0.00%)**	**1/128 (0.78%)**
Coronary artery disease [*1]		
# participants affected / at risk	**0/127 (0.00%)**	**1/128 (0.78%)**
Gastrointestinal disorders		
Lumbar hernia [*1]		
# participants affected / at risk	**1/127 (0.79%)**	**0/128 (0.00%)**
Infections and infestations		
Urosepsis [*1]		
# participants affected / at risk	**0/127 (0.00%)**	**1/128 (0.78%)**
Metabolism and nutrition disorders		
Hypoglycaemia [*1]		
# participants affected / at risk	**1/127 (0.79%)**	**1/128 (0.78%)**
Hyperglycaemia [*1]		
# participants affected / at risk	**0/127 (0.00%)**	**1/128 (0.78%)**
Musculoskeletal and connective tissue disorders		
Arthralgia [*1]		
# participants affected / at risk	**1/127 (0.79%)**	**0/128 (0.00%)**
Back pain [*1]		
# participants affected / at risk	**1/127 (0.79%)**	**0/128 (0.00%)**
Lumbar spinal stenosis [*1]		
# participants affected / at risk	**1/127 (0.79%)**	**0/128 (0.00%)**
Rotator cuff syndrome [*1]		
# participants affected / at risk	**0/127 (0.00%)**	**1/128 (0.78%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Bladder cancer [*1]		
# participants affected / at risk	**0/127 (0.00%)**	**1/128 (0.78%)**
Pancreatic carcinoma [*1]		
# participants affected / at risk	**0/127 (0.00%)**	**1/128 (0.78%)**
Nervous system disorders		

Presyncope * 1		
# participants affected / at risk	**0/127 (0.00%)**	**1/128 (0.78%)**
Respiratory, thoracic and mediastinal disorders		
Asthma * 1		
# participants affected / at risk	**0/127 (0.00%)**	**1/128 (0.78%)**
Skin and subcutaneous tissue disorders		
Urticaria * 1		
# participants affected / at risk	**1/127 (0.79%)**	**0/128 (0.00%)**

* Events were collected by non-systematic assessment

1 Term from vocabulary, MedDRA 13.0

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 + Placebo	Exenatide-subcutaneous injection, 5mcg (4 weeks) followed by 10mcg (16 weeks), twice a day; Placebo-tablet orally once a day.
Exenatide + Sitagliptin	Exenatide-subcutaneous injection, 5mcg (4 weeks) followed by 10mcg (16 weeks), twice a day; Sitagliptin-100mg tablet orally once a day.

Other Adverse Events

	Exenatide + Placebo	Exenatide + Sitagliptin
Total, Other (not including serious) Adverse Events		
# participants affected / at risk	**36/127 (28.35%)**	**28/128 (21.88%)**
Gastrointestinal disorders		
Nausea * 1		
# participants affected / at risk	**20/127 (15.75%)**	**13/128 (10.16%)**
Vomiting * 1		
# participants affected / at risk	**13/127 (10.24%)**	**4/128 (3.13%)**
Infections and infestations		
Nasopharyngitis * 1		
# participants affected / at risk	**11/127 (8.66%)**	**10/128 (7.81%)**
Nervous system disorders		
Headache * 1		
# participants affected / at risk	**6/127 (4.72%)**	**9/128 (7.03%)**

* Events were collected by non-systematic assessment

1 Term from vocabulary, MedDRA 13.0

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):

Violante R, Oliveira JH, Yoon KH, Reed VA, Yu MB, Bachmann OP, Lüdemann J, Chan JY. A randomized non-inferiority study comparing the addition of exenatide twice daily to sitagliptin or switching from sitagliptin to exenatide twice daily in patients with type 2 diabetes experiencing inadequate glycaemic control on metformin and sitagliptin. Diabet Med. 2012 Nov;29(11):e417-24. doi: 10.1111/j.1464-5491.2012.03624.x.

Responsible Party: AstraZeneca
ClinicalTrials.gov Identifier: NCT00870194 History of Changes

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First Submitted:	March 25, 2009
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Results First Submitted:	April 11, 2011
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