Trial record **1 of 1** for: H8O-EW-GWDL

Previous Study | Return to List | Next Study

Efficacy of Once-Weekly Exenatide Versus Once or Twice Daily Insulin Detemir in Patients With Type 2 Diabetes

ClinicalTrials.gov Identifier: NCT01003184

Recruitment Status: Completed
First Posted: October 28, 2009
Results First Posted: December 18, 2012
Last Update Posted: April 7, 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: None (Open Label); Primary Purpose: Treatment
Condition:	Type 2 Diabetes Mellitus
Interventions:	Drug: exenatide once weekly Drug: insulin detemir

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
6 patients who were enrolled and randomized, subsequently discontinued the study before receiving study drug. These patients were not included in analysis.

Reporting Groups

	Description
Exenatide Once Weekly	Exenatide once weekly : subcutaneous injection, 2mg, once a week
Insulin Detemir	Insulin detemir : subcutaneous injection, with dosage titrated according to the detemir label and published titration schedule, once or twice a day

Participant Flow: Overall Study

	Exenatide Once Weekly	**Insulin Detemir**

STARTED	**111**	**111**
Full Analysis Set (FAS)	**111**	**105**
COMPLETED	**92**	**99**
NOT COMPLETED	**19**	**12**
Adverse Event	**12**	**5**
Lost to Follow-up	**1**	**0**
Loss of glucose control	**1**	**1**
Protocol Violation	**3**	**0**
Withdrawal by Subject	**1**	**6**
Physician Decision	**1**	**0**

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 Once Weekly	Exenatide once weekly : subcutaneous injection, 2mg, once a week
Insulin Detemir	Insulin detemir : subcutaneous injection, with dosage titrated according to the detemir label and published titration schedule, once or twice a day
Total	Total of all reporting groups

Baseline Measures

			Total

	Exenatide Once Weekly	Insulin Detemir	
Overall Participants Analyzed [Units: Participants]	**111**	**105**	**216**
Age [Units: Participants]			
<=18 years	**0**	**0**	**0**
Between 18 and 65 years	**74**	**78**	**152**
>=65 years	**37**	**27**	**64**
Age [Units: Years] Mean (Standard Deviation)	**59.2 (9.86)**	**57.8 (9.48)**	**58.5 (9.68)**
Gender [Units: Participants]			
Female	**40**	**33**	**73**
Male	**71**	**72**	**143**
HbA1c [1] [Units: Percentage of total hemoglobin] Mean (Standard Deviation)	**8.4 (0.85)**	**8.4 (0.88)**	**8.4 (0.86)**
[1] At visit 3 (week 0).			
Weight [Units: Kilograms] Mean (Standard Deviation)	**96.7 (17.03)**	**97.9 (15.82)**	**97.3 (16.42)**

Outcome Measures

Hide All Outcome Measures

1. **Primary: Percentage of Patients Achieving Glycosylated Hemoglobin (HbA1c) Concentration ≤7.0% With Weight Loss (≥1.0 kg) at Endpoint (Week 26) [Time Frame: Baseline, Week 26]**

Measure Type	Primary
Measure Title	Percentage of Patients Achieving Glycosylated Hemoglobin (HbA1c) Concentration ≤7.0% With Weight Loss (≥1.0 kg) at Endpoint (Week 26)
Measure Description	The primary endpoint is the percentage of patients achieving HbA1c concentration ≤7.0% with weight loss (≥1.0 kg) at endpoint. The last post-baseline measurement set of both non-missing HbA1c concentration and weight (measured at the same time point, i.e. visit) is used as endpoint value. Patients who do not have a baseline weight measurement, have a protocol violation of baseline HbA1c <=7.0%, and/or have missing post-baseline measurements for HbA1c concentration and/or weight, are included in the analysis as non-responders regarding the primary objective.
Time Frame	Baseline, Week 26

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.
The full analysis set (FAS) includes all data from all randomised patients receiving at least one dose of the study drug according to the treatment the patients were assigned.

Reporting Groups

	Description
Exenatide Once Weekly	Exenatide once weekly : subcutaneous injection, 2mg, once a week
Insulin Detemir	Insulin detemir : subcutaneous injection, with dosage titrated according to the detemir label and published titration schedule, once or twice a day

Measured Values

	Exenatide Once Weekly	**Insulin Detemir**
Participants Analyzed	**111**	**105**
Percentage of Patients Achieving Glycosylated Hemoglobin (HbA1c) Concentration ≤7.0% With Weight Loss (≥1.0 kg) at	**44.1 (34.7 to 53.9)**	**11.4 (6.0 to 19.1)**

Endpoint (Week 26) [Units: Percentage] Number (95% Confidence Interval)		

Statistical Analysis 1 for Percentage of Patients Achieving Glycosylated Hemoglobin (HbA1c) Concentration ≤7.0% With Weight Loss (≥1.0 kg) at Endpoint (Week 26)

Groups [1]	All groups
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	Regression, Logistic
P Value [4]	<.0001
Odds Ratio (OR) [5]	6.60
95% Confidence Interval	3.17 to 13.73

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

Primary objective: to test hypothesis that the percentage of patients with HbA1c ≤7.0% with weight loss (≥1.0 kg) after exenatide QW is superior to insulin detemir.

Sample size estimation: based on the test for difference in percentage between Exenatide QW and insulin detemir. Assuming: common drop-out rate 20%, response rate at endpoint 50% in the exenatide QW group and 25% in the insulin detemir group; 5% significance. 214 patients will provide 90% power to detect a difference.

[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:

Logistic regression model includes treatment group, use of SU (yes/no), baseline HbA1c and baseline weight as main factors.

[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:

No text entered.

2. Secondary: Percentage of Patients Who Have Achieved HbA1c ≤7.4% With Weight Loss (≥1.0 kg) at Endpoint (Week 26) [Time Frame: Baseline, Week 26]

Measure Type	Secondary
Measure Title	Percentage of Patients Who Have Achieved HbA1c ≤7.4% With Weight Loss (≥1.0 kg) at Endpoint (Week 26)
Measure Description	Percentage of patients who have achieved HbA1c ≤7.4% with weight loss (≥1.0 kg) at endpoint (Week 26)
Time Frame	Baseline, Week 26

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.
The analysis was done for the FAS population (as randomised). For secondary analyses including both final HbA1c concentration and change in weight the last post-baseline measurement set of both non-missing HbA1c and weight was used as endpoint value.

Reporting Groups

	Description
Exenatide Once Weekly	Exenatide once weekly : subcutaneous injection, 2mg, once a week
Insulin Detemir	Insulin detemir : subcutaneous injection, with dosage titrated according to the detemir label and published titration schedule, once or twice a day

Measured Values

	Exenatide Once Weekly	**Insulin Detemir**
Participants Analyzed	**107**	**101**

Percentage of Patients Who Have Achieved HbA1c ≤7.4% With Weight Loss (≥1.0 kg) at Endpoint (Week 26) [Units: Percentage] Number (95% Confidence Interval)	**58.9** **(49.0 to 68.3)**	**17.8** **(10.9 to 26.7)**

Statistical Analysis 1 for Percentage of Patients Who Have Achieved HbA1c ≤7.4% With Weight Loss (≥1.0 kg) at Endpoint (Week 26)

Groups [1]	All groups
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	Regression, Logistic
P Value [4]	<.0001
Odds Ratio (OR) [5]	7.06
95% Confidence Interval	3.64 to 13.70

[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:

Logistic regression model includes the independent variables treatment group, use of SU (yes/no), baseline HbA1c and baseline weight.

[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:

No text entered.

3. Secondary: Change in HbA1c From Baseline to Week 26 [Time Frame: Baseline, Week 26]

Measure Type	Secondary

Measure Title	Change in HbA1c From Baseline to Week 26
Measure Description	Change in HbA1c from baseline to week 26
Time Frame	Baseline, Week 26

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.
The analysis was done for the FAS population (as randomised).

Reporting Groups

	Description
Exenatide Once Weekly	Exenatide once weekly : subcutaneous injection, 2mg, once a week
Insulin Detemir	Insulin detemir : subcutaneous injection, with dosage titrated according to the detemir label and published titration schedule, once or twice a day

Measured Values

	Exenatide Once Weekly	**Insulin Detemir**
Participants Analyzed	**95**	**96**
Change in HbA1c From Baseline to Week 26 [Units: Percentage of total hemoglobin] Least Squares Mean (Standard Error)	**-1.32 (0.076)**	**-0.91 (0.077)**

Statistical Analysis 1 for Change in HbA1c From Baseline to Week 26

Groups [1]	All groups
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	Mixed Models Analysis
P Value [4]	0.0001

Least Squares Mean Difference [5]	-0.41
95% Confidence Interval	-0.62 to -0.20
Standard Error of the mean	(0.104)

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

Mixed model repeated measures (MMRM) includes baseline value as covariate, study treatment, use of SU (yes/no), week of visit and treatment-by-week interaction as fixed effects and patient and error as random effects.

[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] Other relevant estimation information:

No text entered.

4. Secondary: Change in Body Weight From Baseline to Week 26 [Time Frame: Baseline, Week 26]

Measure Type	Secondary
Measure Title	Change in Body Weight From Baseline to Week 26
Measure Description	Change in body weight from baseline to week 26
Time Frame	Baseline, Week 26

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.
The analysis was done for the FAS population (as randomised).

Reporting Groups

	Description
Exenatide Once Weekly	Exenatide once weekly : subcutaneous injection, 2mg, once a week
Insulin Detemir	Insulin detemir : subcutaneous injection, with dosage titrated according to the detemir label and published titration schedule, once or twice a day

Measured Values

	Exenatide Once Weekly	Insulin Detemir
Participants Analyzed	**96**	**98**
Change in Body Weight From Baseline to Week 26 [Units: Kilograms] Least Squares Mean (Standard Error)	**-2.79 (0.347)**	**0.88 (0.351)**

Statistical Analysis 1 for Change in Body Weight From Baseline to Week 26

Groups [1]	All groups
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	Mixed Models Analysis
P Value [4]	<.0001
Least Squares Mean Difference [5]	-3.67
95% Confidence Interval	-4.63 to -2.71
Standard Error of the mean	(0.488)

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

Mixed model repeated measures MMRM) includes baseline value as covariate, study treatment, use of SU (yes/no), baseline HbA1c stratum, week of visit and treatment-by-week interaction as fixed effects and patient and error as random effects.

[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] Other relevant estimation information:

No text entered.

5. Secondary: Percentage of Patients Achieving HbA1c ≤7.4% at Endpoint [Time Frame: Week 26]

Measure Type	Secondary
Measure Title	Percentage of Patients Achieving HbA1c ≤7.4% at Endpoint
Measure Description	Percentage of patients who have achieved HbA1c ≤.7.4% at endpoint
Time Frame	Week 26

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.
The analysis was done for the FAS population (as randomised). Patients with baseline HbA1c ≤7.0% and/or no post-baseline HbA1c measurement were regarded as non-responders.

Reporting Groups

	Description
Exenatide Once Weekly	Exenatide once weekly : subcutaneous injection, 2mg, once a week
Insulin Detemir	Insulin detemir : subcutaneous injection, with dosage titrated according to the detemir label and published titration schedule, once or twice a day

Measured Values

	Exenatide Once Weekly	Insulin Detemir
Participants Analyzed	**111**	**105**
Percentage of Patients Achieving HbA1c ≤7.4% at Endpoint [Units: Percentage] Number (95% Confidence Interval)	**66.7** **(57.1 to 75.3)**	**54.3** **(44.3 to 64.0)**

Statistical Analysis 1 for Percentage of Patients Achieving HbA1c ≤7.4% at Endpoint

Groups [1]	All groups
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	Regression, Logistic
P Value [4]	0.0497
Odds Ratio (OR) [5]	1.79
95% Confidence Interval	1.00 to 3.18

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

Logistic regression model includes independent variables treatment group, use of SU (yes/no), and baseline HbA1c.

[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] Other relevant estimation information:

No text entered.

6. Secondary:

Percentage of Patients Achieving ≤7.0% at Endpoint [Time Frame: Week 26]

Measure Type	Secondary
Measure Title	Percentage of Patients Achieving ≤7.0% at Endpoint
Measure Description	Percentage of patients achieving ≤7.0% at endpoint.
Time Frame	Week 26

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.
The analysis was done for the FAS population (as randomised). Patients with baseline HbA1c ≤7.0% and/or no post-baseline HbA1c measurement were regarded as non-responders.

Reporting Groups

	Description
Exenatide Once Weekly	Exenatide once weekly : subcutaneous injection, 2mg, once a week
Insulin Detemir	Insulin detemir : subcutaneous injection, with dosage titrated according to the detemir label and published titration schedule, once or twice a day

Measured Values

	Exenatide Once Weekly	**Insulin Detemir**
Participants Analyzed	**111**	**105**
Percentage of Patients Achieving ≤7.0% at Endpoint [Units: Percentage] Number (95% Confidence Interval)	**51.4** **(41.7 to 61.0)**	**34.3** **(25.3 to 44.2)**

Statistical Analysis 1 for Percentage of Patients Achieving ≤7.0% at Endpoint

Groups [1]	All groups
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	Regression, Logistic
P Value [4]	0.0074
Odds Ratio (OR) [5]	2.21
95% Confidence Interval	1.24 to 3.96

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

Logistic regression model includes independent variables treatment group, use of SU (yes/no), and baseline HbA1c.

[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] Other relevant estimation information:

No text entered.

7. Secondary: Percentage of Patients Achieving ≤6.5% at Endpoint [Time Frame: Week 26]

Measure Type	Secondary
Measure Title	Percentage of Patients Achieving ≤6.5% at Endpoint
Measure Description	Percentage of patients achieving HbA1c ≤6.5% at endpoint
Time Frame	Week 26

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.
The analysis was done for the FAS population (as randomised). Patients with baseline HbA1c ≤7.0% and/or no post-baseline HbA1c measurement were regarded as non-responders.

Reporting Groups

	Description
Exenatide Once Weekly	Exenatide once weekly : subcutaneous injection, 2mg, once a week
Insulin Detemir	Insulin detemir : subcutaneous injection, with dosage titrated according to the detemir label and published titration schedule, once or twice a day

Measured Values

	Exenatide Once Weekly	**Insulin Detemir**
Participants Analyzed	**111**	**105**
Percentage of Patients Achieving ≤6.5% at Endpoint [Units: Percentage] Number (95% Confidence Interval)	**27.9** **(19.8 to 37.2)**	**7.6** **(3.3 to 14.5)**

Statistical Analysis 1 for Percentage of Patients Achieving ≤6.5% at Endpoint

Groups [1]	All groups
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	Regression, Logistic
P Value [4]	0.0002
Odds Ratio (OR) [5]	4.89
95% Confidence Interval	2.10 to 11.35

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

Logistic regression model includes independent variables treatment group, use of SU (yes/no), and baseline HbA1c.

[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] Other relevant estimation information:

No text entered.

8. Secondary: Change in Fasting Serum Glucose From Baseline to Endpoint (Week 26). [Time Frame: Baseline, Week 26]

Measure Type	Secondary
Measure Title	Change in Fasting Serum Glucose From Baseline to Endpoint (Week 26).
Measure Description	Change in fasting serum glucose from baseline to endpoint (Week 26).
Time Frame	Baseline, Week 26

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.
The analysis was done for the FAS population (as randomised). The last observation carried forward (LOCF) of post baseline values was used for this analysis.

Reporting Groups

	Description
Exenatide Once Weekly	

	Exenatide once weekly : subcutaneous injection, 2mg, once a week
Insulin Detemir	Insulin detemir : subcutaneous injection, with dosage titrated according to the detemir label and published titration schedule, once or twice a day

Measured Values

	Exenatide Once Weekly	**Insulin Detemir**
Participants Analyzed	**108**	**104**
Change in Fasting Serum Glucose From Baseline to Endpoint (Week 26). [Units: mmol/L] Least Squares Mean (Standard Error)	**-2.33 (0.191)**	**-2.43 (0.196)**

Statistical Analysis 1 for Change in Fasting Serum Glucose From Baseline to Endpoint (Week 26).

Groups [1]	All groups
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	ANCOVA
P Value [4]	0.6993
Least Squares Mean Difference [5]	0.10
95% Confidence Interval	-0.41 to 0.61
Standard Error of the mean	(0.257)

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

ANCOVA model includes treatment group, baseline value, use of SU (yes/no) and baseline HbA1c stratum as factors.

[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] Other relevant estimation information:

No text entered.

9. Secondary: Changes in Systolic Blood Pressure From Baseline to Week 26 [Time Frame: Baseline, Week 26]

Measure Type	Secondary
Measure Title	Changes in Systolic Blood Pressure From Baseline to Week 26
Measure Description	Change in systolic blood pressure from baseline to Week 26
Time Frame	Baseline, Week 26

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.
The analysis was done for the FAS population (as randomised).

Reporting Groups

	Description
Exenatide Once Weekly	Exenatide once weekly : subcutaneous injection, 2mg, once a week
Insulin Detemir	Insulin detemir : subcutaneous injection, with dosage titrated according to the detemir label and published titration schedule, once or twice a day

Measured Values

	Exenatide Once Weekly	**Insulin Detemir**
Participants Analyzed	**95**	**98**

Changes in Systolic Blood Pressure From Baseline to Week 26 [Units: mmHg] Least Squares Mean (Standard Error)	**-7.37 (1.342)**	**-2.65 (1.339)**

Statistical Analysis 1 for Changes in Systolic Blood Pressure From Baseline to Week 26

Groups [1]	All groups
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	Mixed Models Analysis
P Value [4]	0.0116
Least Squares Mean Difference [5]	-4.72
95% Confidence Interval	-8.37 to -1.07
Standard Error of the mean	(1.853)

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

Mixed model repeated measures (MMRM) includes baseline value as covariate, study treatment, use of SU (yes/no), baseline HbA1c stratum, week of visit and treatment-by-week interaction as fixed effects and patient and error as random effects.

[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] Other relevant estimation information:

No text entered.

10. Secondary: Change in Diastolic Blood Pressure From Baseline to Week 26. [Time Frame: Baseline, Week 26]

Measure Type	Secondary
Measure Title	Change in Diastolic Blood Pressure From Baseline to Week 26.
Measure Description	Change in diastolic blood pressure from baseline to week 26.
Time Frame	Baseline, Week 26

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.
The analysis was done for the FAS population (as randomised).

Reporting Groups

	Description
Exenatide Once Weekly	Exenatide once weekly : subcutaneous injection, 2mg, once a week
Insulin Detemir	Insulin detemir : subcutaneous injection, with dosage titrated according to the detemir label and published titration schedule, once or twice a day

Measured Values

	Exenatide Once Weekly	**Insulin Detemir**
Participants Analyzed	**95**	**98**
Change in Diastolic Blood Pressure From Baseline to Week 26. [Units: mmHg] Least Squares Mean (Standard Error)	**-0.79 (0.855)**	**-0.34 (0.859)**

Statistical Analysis 1 for Change in Diastolic Blood Pressure From Baseline to Week 26.

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

Statistical Method [3]	Mixed Models Analysis
P Value [4]	0.7034
Least Squares Mean Difference [5]	-0.45
95% Confidence Interval	-2.77 to 1.88
Standard Error of the mean	(1.179)

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

Mixed model repeated measures (MMRM) includes baseline value as covariate, study treatment, use of SU (yes/no), baseline HbA1c stratum, week of visit and treatment-by-week interaction as fixed effects and patient and error as random effects.

[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] Other relevant estimation information:

No text entered.

11. Secondary: Change in Total Cholesterol From Baseline to Endpoint (Week 26). [Time Frame: Baseline, Week 26]

Measure Type	Secondary
Measure Title	Change in Total Cholesterol From Baseline to Endpoint (Week 26).
Measure Description	Change in total cholesterol from baseline to endpoint (week 26).
Time Frame	Baseline, Week 26

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.
The analysis was done for the FAS population (as randomised). The last observation carried forward (LOCF) of post baseline values was used for this analysis.

Reporting Groups

	Description
Exenatide Once Weekly	Exenatide once weekly : subcutaneous injection, 2mg, once a week
Insulin Detemir	Insulin detemir : subcutaneous injection, with dosage titrated according to the detemir label and published titration schedule, once or twice a day

Measured Values

	Exenatide Once Weekly	**Insulin Detemir**
Participants Analyzed	**105**	**100**
Change in Total Cholesterol From Baseline to Endpoint (Week 26). [Units: mmol/L] Least Squares Mean (Standard Error)	**-0.09 (0.067)**	**0.06 (0.068)**

Statistical Analysis 1 for Change in Total Cholesterol From Baseline to Endpoint (Week 26).

Groups [1]	All groups
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	ANCOVA
P Value [4]	0.1061
Least Squares Mean Difference [5]	-0.15
95% Confidence Interval	-0.32 to 0.03

Standard Error of the mean	(0.090)

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

ANCOVA model includes treatment group, baseline value, use of SU (yes/no) and baseline HbA1c stratum as factors.

[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] Other relevant estimation information:

No text entered.

12. Secondary: Change in High-density Lipoprotein (HDL) Cholesterol From Baseline to Endpoint (Week 26). [Time Frame: Baseline, Week 26]

Measure Type	Secondary
Measure Title	Change in High-density Lipoprotein (HDL) Cholesterol From Baseline to Endpoint (Week 26).
Measure Description	Change in High-density lipoprotein (HDL) cholesterol from baseline to endpoint (week 26).
Time Frame	Baseline, Week 26

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.
The analysis was done for the FAS population (as randomised). The last observation carried forward (LOCF) of post baseline values was used for this analysis.

Reporting Groups

	Description
Exenatide Once Weekly	Exenatide once weekly : subcutaneous injection, 2mg, once a week
Insulin Detemir	Insulin detemir : subcutaneous injection, with dosage titrated according to the detemir label and published titration schedule, once or twice a day

Measured Values

	Exenatide Once Weekly	Insulin Detemir
Participants Analyzed	**105**	**100**
Change in High-density Lipoprotein (HDL) Cholesterol From Baseline to Endpoint (Week 26). [Units: mmol/L] Least Squares Mean (Standard Error)	**0.02 (0.014)**	**0.04 (0.015)**

Statistical Analysis 1 for Change in High-density Lipoprotein (HDL) Cholesterol From Baseline to Endpoint (Week 26).

Groups [1]	All groups
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	ANCOVA
P Value [4]	0.4638
Least Squares Mean Difference [5]	-0.01
95% Confidence Interval	-0.05 to 0.02
Standard Error of the mean	(0.020)

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

ANCOVA model includes treatment group, baseline value, use of SU (yes/no) and baseline HbA1c stratum as factors.

[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] Other relevant estimation information:

No text entered.

13. Secondary: Change in Triglycerides From Baseline to Endpoint (Week 26). [Time Frame: Baseline, Week 26]

Measure Type	Secondary
Measure Title	Change in Triglycerides From Baseline to Endpoint (Week 26).
Measure Description	Change in triglycerides from baseline to endpoint (week 26).
Time Frame	Baseline, Week 26

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.
The analysis was done for the FAS population (as randomised). The last observation carried forward (LOCF) of post baseline values was used for this analysis.

Reporting Groups

	Description
Exenatide Once Weekly	Exenatide once weekly : subcutaneous injection, 2mg, once a week
Insulin Detemir	Insulin detemir : subcutaneous injection, with dosage titrated according to the detemir label and published titration schedule, once or twice a day

Measured Values

	Exenatide Once Weekly	Insulin Detemir
Participants Analyzed	**105**	**100**
Change in Triglycerides From Baseline to Endpoint (Week 26). [Units: mmol/L] Least Squares Mean (Standard Error)	**-0.01 (0.079)**	**-0.08 (0.081)**

Statistical Analysis 1 for Change in Triglycerides From Baseline to Endpoint (Week 26).

Groups [1]	All groups
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	ANCOVA
P Value [4]	0.4967
Least Squares Mean Difference [5]	0.07
95% Confidence Interval	-0.14 to 0.28
Standard Error of the mean	(0.107)

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

ANCOVA model includes treatment group, baseline value, use of SU (yes/no) and baseline HbA1c stratum as factors.

[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] Other relevant estimation information:

No text entered.

14. Secondary: Hypoglycemia Rate Per Year [Time Frame: Baseline, Week 26]

Measure Type	Secondary
Measure Title	Hypoglycemia Rate Per Year
Measure Description	All confirmed hypoglycemia episodes defined as either minor (any time a patient feels that he or she is experiencing a sign or symptom associated with hypoglycaemia and blood glucose (BG) <3.0 mmol/L (54 mg/dL)) or major (any hypoglycaemic episode with symptoms consistent with hypoglycaemia, resulting in loss of consciousness or seizure, and shows prompt recovery in response to administration of glucagon or glucose, or BG measurement < 3.0mmol/L is available and the patient is not capable of self-treating were taken into account.
Time Frame	Baseline, Week 26

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 (as randomized).

Reporting Groups

	Description
Exenatide Once Weekly	Exenatide once weekly : subcutaneous injection, 2mg, once a week
Insulin Detemir	Insulin detemir : subcutaneous injection, with dosage titrated according to the detemir label and published titration schedule, once or twice a day

Measured Values

	Exenatide Once Weekly	**Insulin Detemir**
Participants Analyzed	**111**	**105**

Hypoglycemia Rate Per Year [Units: Events per subject-year] Number (95% Confidence Interval)	**0.06** **(0.02 to 0.20)**	**0.10** **(0.03 to 0.30)**

Statistical Analysis 1 for Hypoglycemia Rate Per Year

Groups [1]	All groups
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	Poisson regression
P Value [4]	0.3247
Ratio [5]	0.58
95% Confidence Interval	0.19 to 1.72
Standard Error of the mean	(0.322)

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

The number of episodes by patient were compared between treatment groups using a poisson model with effects for treatment and baseline HbA1c and the logarithm of the days of exposure as the offset variable.

[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] Other relevant estimation information:

No text entered.

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Exenatide Once Weekly	Exenatide once weekly : subcutaneous injection, 2mg, once a week
Insulin Detemir	Insulin detemir : subcutaneous injection, with dosage titrated according to the detemir label and published titration schedule, once or twice a day

Serious Adverse Events

	Exenatide Once Weekly	Insulin Detemir
Total, Serious Adverse Events		
# participants affected / at risk	**6/111 (5.41%)**	**6/105 (5.71%)**
Cardiac disorders		
Atrioventricular block second degree [1]		
# participants affected / at risk	**1/111 (0.90%)**	**0/105 (0.00%)**
Ventricular extrasystoles [1]		
# participants affected / at risk	**1/111 (0.90%)**	**0/105 (0.00%)**
General disorders		
Chest discomfort [1]		
# participants affected / at risk	**1/111 (0.90%)**	**1/105 (0.95%)**
Chest pain [1]		
# participants affected / at risk	**0/111 (0.00%)**	**2/105 (1.90%)**
Infections and infestations		
Pneumonia [1]		
# participants affected / at risk	**0/111 (0.00%)**	**1/105 (0.95%)**
Injury, poisoning and procedural complications		

Joint sprain [1]		
# participants affected / at risk	**1/111 (0.90%)**	**0/105 (0.00%)**
Investigations		
Blood amylase increased [1]		
# participants affected / at risk	**1/111 (0.90%)**	**0/105 (0.00%)**
Lipase increased [1]		
# participants affected / at risk	**1/111 (0.90%)**	**0/105 (0.00%)**
Metabolism and nutrition disorders		
Hyperglycaemia [1]		
# participants affected / at risk	**0/111 (0.00%)**	**1/105 (0.95%)**
Musculoskeletal and connective tissue disorders		
Bursitis [1]		
# participants affected / at risk	**1/111 (0.90%)**	**0/105 (0.00%)**
Myositis [1]		
# participants affected / at risk	**1/111 (0.90%)**	**0/105 (0.00%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Small cell lung cancer stage unspecified [1]		
# participants affected / at risk	**0/111 (0.00%)**	**1/105 (0.95%)**
Renal and urinary disorders		
Renal injury [1]		
# participants affected / at risk	**0/111 (0.00%)**	**1/105 (0.95%)**

1 Term from vocabulary, MedDRA 14.0

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 Once Weekly	Exenatide once weekly : subcutaneous injection, 2mg, once a week
Insulin Detemir	Insulin detemir : subcutaneous injection, with dosage titrated according to the detemir label and published titration schedule, once or twice a day

Other Adverse Events

	Exenatide Once Weekly	**Insulin Detemir**
Total, Other (not including serious) Adverse Events		
# participants affected / at risk	**87/111 (78.38%)**	**58/105 (55.24%)**
Gastrointestinal disorders		
Nausea [1]		
# participants affected / at risk	**53/111 (47.75%)**	**12/105 (11.43%)**
Diarrhoea [1]		
# participants affected / at risk	**19/111 (17.12%)**	**11/105 (10.48%)**
Vomiting [1]		
# participants affected / at risk	**16/111 (14.41%)**	**9/105 (8.57%)**
Constipation [1]		
# participants affected / at risk	**10/111 (9.01%)**	**3/105 (2.86%)**
Dyspepsia [1]		
# participants affected / at risk	**7/111 (6.31%)**	**1/105 (0.95%)**
General disorders		
Injection site nodule [1]		
# participants affected / at risk	**22/111 (19.82%)**	**0/105 (0.00%)**

Injection site pruritus [1]		
# participants affected / at risk	**12/111 (10.81%)**	**1/105 (0.95%)**
Malaise [1]		
# participants affected / at risk	**6/111 (5.41%)**	**2/105 (1.90%)**
Infections and infestations		
Nasopharyngitis [1]		
# participants affected / at risk	**23/111 (20.72%)**	**31/105 (29.52%)**
Lower respiratory tract infection [1]		
# participants affected / at risk	**5/111 (4.50%)**	**6/105 (5.71%)**
Influenza [1]		
# participants affected / at risk	**2/111 (1.80%)**	**6/105 (5.71%)**
Musculoskeletal and connective tissue disorders		
Back pain [1]		
# participants affected / at risk	**9/111 (8.11%)**	**7/105 (6.67%)**
Musculoskeletal [1]		
# participants affected / at risk	**7/111 (6.31%)**	**2/105 (1.90%)**
Pain in extremity [1]		
# participants affected / at risk	**6/111 (5.41%)**	**3/105 (2.86%)**
Arthralgia [1]		
# participants affected / at risk	**5/111 (4.50%)**	**6/105 (5.71%)**
Nervous system disorders		
Headache [1]		
# participants affected / at risk	**23/111 (20.72%)**	**15/105 (14.29%)**
Respiratory, thoracic and mediastinal disorders		
Cough [1]		
# participants affected / at risk	**7/111 (6.31%)**	**9/105 (8.57%)**
Oropharyngeal pain [1]		
# participants affected / at risk	**4/111 (3.60%)**	**8/105 (7.62%)**

1 Term from vocabulary, MedDRA 14.0

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 **NOT** 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.

Results Point of Contact:

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Responsible Party:	AstraZeneca
ClinicalTrials.gov Identifier:	NCT01003184 History of Changes
Other Study ID Numbers:	**H8O-EW-GWDL**
First Submitted:	October 15, 2009
First Posted:	October 28, 2009
Results First Submitted:	November 20, 2012
Results First Posted:	December 18, 2012
Last Update Posted:	April 7, 2015