Trial record **1 of 1** for: H8O-MC-GWCD

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A Study to Assess the Effect of Exenatide Treatment on Mean 24-Hour Heart Rate in Patients With Type 2 Diabetes

ClinicalTrials.gov Identifier: NCT00516074

Recruitment Status: Completed
First Posted: August 14, 2007
Results First Posted: June 12, 2009
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: Double (Participant, Investigator); Primary Purpose: Treatment
Condition:	Type 2 Diabetes Mellitus
Interventions:	Drug: exenatide Drug: 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 BID	5mcg exenatide twice daily for 4 weeks, and then 10mcg exenatide twice daily for the remaining 8 weeks of the study.
Placebo	Placebo injection twice daily (volume equivalent to the exenatide injection in the experimental arm).

Participant Flow: Overall Study

	Exenatide BID	**Placebo**

STARTED	**28**	**26**
COMPLETED	**22**	**23**
NOT COMPLETED	**6**	**3**
Adverse Event	**0**	**1**
Subject Decision	**4**	**2**
Loss of Glucose Control	**2**	**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 BID	5mcg exenatide twice daily for 4 weeks, and then 10mcg exenatide twice daily for the remaining 8 weeks of the study.
Placebo	Placebo injection twice daily (volume equivalent to the exenatide injection in the experimental arm).
Total	Total of all reporting groups

Baseline Measures

	Exenatide BID	**Placebo**	**Total**
Overall Participants Analyzed [Units: Participants]	**28**	**26**	**54**
Age [Units: Participants]			

<=18 years	**0**	**0**	**0**
Between 18 and 65 years	**23**	**23**	**46**
>=65 years	**5**	**3**	**8**
Age [Units: Years] Mean (Standard Deviation)	**56.62 (10.90)**	**54.14 (10.13)**	**55.43 (10.51)**
Gender [Units: Participants]			
Female	**9**	**15**	**24**
Male	**19**	**11**	**30**

Outcome Measures

Hide All Outcome Measures

1. **Primary: Change in Mean 24-hour Heart Rate From Baseline to Endpoint [Time Frame: 12 weeks]**

Measure Type	Primary
Measure Title	Change in Mean 24-hour Heart Rate From Baseline to Endpoint
Measure Description	Change from baseline to endpoint in average heart rate measured over 24 hours by an ambulatory blood pressure monitor.
Time Frame	12 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.
Intent to treat; Last observation carried forward

Reporting Groups

	Description

Exenatide BID	5mcg exenatide twice daily for 4 weeks, and then 10mcg exenatide twice daily for the remaining 8 weeks of the study.
Placebo	Placebo injection twice daily (volume equivalent to the exenatide injection in the experimental arm).

Measured Values

	Exenatide BID	**Placebo**
Participants Analyzed	**26**	**25**
Change in Mean 24-hour Heart Rate From Baseline to Endpoint [Units: Beats per minute] Least Squares Mean (Standard Error)		
Baseline (Week 0)	**74.83 (2.04)**	**74.47 (2.08)**
Change at endpoint (Week 12)	**2.14 (1.39)**	**-0.71 (1.42)**

Statistical Analysis 1 for Change in Mean 24-hour Heart Rate From Baseline to Endpoint

Groups [1]	All groups
Statistical Test Type [2]	Non-Inferiority or Equivalence
Statistical Method [3]	ANCOVA
P Value [4]	0.1585

[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:

Approximately 25 subjects were intended to be randomized to both the exenatide and placebo arms. Assuming an approximate 24% dropout rate, 19 patients per treatment arm would complete the study. A sample of 19 patients per treatment group would provide 90% power to detect a 10 bpm difference between treatment groups in change in daily mean heart rate from baseline.

[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: Change in Daytime Heart Rate From Baseline to Endpoint [Time Frame: 12 weeks]

Measure Type	Secondary
Measure Title	Change in Daytime Heart Rate From Baseline to Endpoint
Measure Description	Change from baseline to endpoint in daytime heart rate as measured by an ambulatory blood pressure monitor
Time Frame	12 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.
Intent to treat; Last observation carried forward

Reporting Groups

	Description
Exenatide BID	5mcg exenatide twice daily for 4 weeks, and then 10mcg exenatide twice daily for the remaining 8 weeks of the study.
Placebo	Placebo injection twice daily (volume equivalent to the exenatide injection in the experimental arm).

Measured Values

	Exenatide BID	**Placebo**
Participants Analyzed	**26**	**25**
Change in Daytime Heart Rate From Baseline to Endpoint [Units: Beats per minute] Least Squares Mean (Standard Error)		

Baseline (Week 0)	**75.97 (2.22)**	**75.37 (2.26)**
Change at endpoint (Week 12)	**2.35 (1.59)**	**-0.87 (1.62)**

Statistical Analysis 1 for Change in Daytime Heart Rate From Baseline to Endpoint

Groups [1]	All groups
Statistical Test Type [2]	Non-Inferiority or Equivalence
Statistical Method [3]	ANCOVA
P Value [4]	0.1624

[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:

Power calculation for the primary endpoint is described as part of the primary endpoint information above.

[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: Change in Nighttime (2400-0600) Heart Rate From Baseline to Endpoint [Time Frame: 12 weeks]

Measure Type	Secondary
Measure Title	Change in Nighttime (2400-0600) Heart Rate From Baseline to Endpoint
Measure Description	Change from baseline to endpoint in nighttime (2400-0600) heart rate as measured by an ambulatory blood pressure monitor
Time Frame	12 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.
Intent to treat; Last observation carried forward

Reporting Groups

	Description
Exenatide BID	5mcg exenatide twice daily for 4 weeks, and then 10mcg exenatide twice daily for the remaining 8 weeks of the study.
Placebo	Placebo injection twice daily (volume equivalent to the exenatide injection in the experimental arm).

Measured Values

	Exenatide BID	**Placebo**
Participants Analyzed	**26**	**25**
Change in Nighttime (2400-0600) Heart Rate From Baseline to Endpoint [Units: Beats per minute] Least Squares Mean (Standard Error)		
Baseline (Week 0)	**71.54 (2.12)**	**71.77 (2.16)**
Change at endpoint (Week 12)	**1.43 (1.79)**	**-0.28 (1.83)**

Statistical Analysis 1 for Change in Nighttime (2400-0600) Heart Rate From Baseline to Endpoint

Groups [1]	All groups
Statistical Test Type [2]	Non-Inferiority or Equivalence
Statistical Method [3]	ANCOVA
P Value [4]	0.5077

[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:

Power calculation for the primary endpoint is described as part of the primary endpoint information above.

[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 Mean 24 Hour Systolic Blood Pressure From Baseline to Endpoint [Time Frame: 12 weeks]

Measure Type	Secondary
Measure Title	Change in Mean 24 Hour Systolic Blood Pressure From Baseline to Endpoint
Measure Description	Change from baseline to endpoint in average systolic blood pressure measured over 24 hours by an ambulatory blood pressure monitor
Time Frame	12 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.
Intent to treat; Last observation carried forward

Reporting Groups

	Description
Exenatide BID	5mcg exenatide twice daily for 4 weeks, and then 10mcg exenatide twice daily for the remaining 8 weeks of the study.
Placebo	Placebo injection twice daily (volume equivalent to the exenatide injection in the experimental arm).

Measured Values

	Exenatide BID	Placebo
Participants Analyzed	**26**	**25**
Change in Mean 24 Hour Systolic Blood Pressure From Baseline to Endpoint [Units: mmHg] Least Squares Mean (Standard Error)		
Baseline (Week 0)	**126.61 (3.04)**	**119.93 (3.10)**
Change at endpoint (Week 12)	**-0.81 (2.67)**	**-0.34 (2.72)**

Statistical Analysis 1 for Change in Mean 24 Hour Systolic Blood Pressure From Baseline to Endpoint

Groups [1]	All groups
Statistical Test Type [2]	Non-Inferiority or Equivalence
Statistical Method [3]	ANCOVA
P Value [4]	0.9034

[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:

Power calculation for the primary endpoint is described as part of the primary endpoint information above.

[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 Mean 24 Hour Diastolic Blood Pressure From Baseline to Endpoint [Time Frame: 12 weeks]

Measure Type	Secondary
Measure Title	Change in Mean 24 Hour Diastolic Blood Pressure From Baseline to Endpoint
Measure Description	Change from baseline to endpoint in average diastolic blood pressure measured over 24 hours by an ambulatory blood pressure monitor
Time Frame	12 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.
Intent to treat; Last observation carried forward

Reporting Groups

	Description
Exenatide BID	5mcg exenatide twice daily for 4 weeks, and then 10mcg exenatide twice daily for the remaining 8 weeks of the study.
Placebo	Placebo injection twice daily (volume equivalent to the exenatide injection in the experimental arm).

Measured Values

	Exenatide BID	**Placebo**
Participants Analyzed	**26**	**25**
Change in Mean 24 Hour Diastolic Blood Pressure From Baseline to Endpoint [Units: mmHg] Least Squares Mean (Standard Error)		
Baseline (Week 0)	**75.70 (2.05)**	**70.54 (2.09)**

Change at endpoint (Week 12)	**-0.60 (1.49)**	**-2.34 (1.52)**

Statistical Analysis 1 for Change in Mean 24 Hour Diastolic Blood Pressure From Baseline to Endpoint

Groups [1]	All groups
Statistical Test Type [2]	Non-Inferiority or Equivalence
Statistical Method [3]	ANCOVA
P Value [4]	0.4270

[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:

Power calculation for the primary endpoint is described as part of the primary endpoint information above.

[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 Hemoglobin A1c (HbA1c) From Baseline to Endpoint [Time Frame: 12 weeks]

Measure Type	Secondary
Measure Title	Change in Hemoglobin A1c (HbA1c) From Baseline to Endpoint
Measure Description	Change from baseline to endpoint in HbA1c
Time Frame	12 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.
Intent to treat; Last observation carried forward

Reporting Groups

	Description
Exenatide BID	5mcg exenatide twice daily for 4 weeks, and then 10mcg exenatide twice daily for the remaining 8 weeks of the study.
Placebo	Placebo injection twice daily (volume equivalent to the exenatide injection in the experimental arm).

Measured Values

	Exenatide BID	**Placebo**
Participants Analyzed	**27**	**25**
Change in Hemoglobin A1c (HbA1c) From Baseline to Endpoint [Units: Percent] Least Squares Mean (Standard Error)		
Baseline (Week 0)	**7.50 (0.16)**	**7.11 (0.17)**
Change at endpoint (Week 12)	**-0.15 (0.16)**	**0.12 (0.17)**

Statistical Analysis 1 for Change in Hemoglobin A1c (HbA1c) From Baseline to Endpoint

Groups [1]	All groups
Statistical Test Type [2]	Non-Inferiority or Equivalence
Statistical Method [3]	ANCOVA
P Value [4]	0.2600

[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:

Power calculation for the primary endpoint is described as part of the primary endpoint information above.

[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 BID	5mcg exenatide twice daily for 4 weeks, and then 10mcg exenatide twice daily for the remaining 8 weeks of the study.
Placebo	Placebo injection twice daily (volume equivalent to the exenatide injection in the experimental arm).

Serious Adverse Events

	Exenatide BID	Placebo
Total, Serious Adverse Events		
# participants affected	**1**	**1**
Injury, poisoning and procedural complications		
Rib fracture † 1		
# participants affected / at risk	**1/28 (3.57%)**	**0/26 (0.00%)**
Psychiatric disorders		

Depression † 1		
# participants affected / at risk	**0/28 (0.00%)**	**1/26 (3.85%)**

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA 11.0

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 BID	5mcg exenatide twice daily for 4 weeks, and then 10mcg exenatide twice daily for the remaining 8 weeks of the study.
Placebo	Placebo injection twice daily (volume equivalent to the exenatide injection in the experimental arm).

Other Adverse Events

	Exenatide BID	**Placebo**
Total, Other (not including serious) Adverse Events		
# participants affected	**18**	**21**
Gastrointestinal disorders		
Nausea † 1		
# participants affected / at risk	**10/28 (35.71%)**	**5/26 (19.23%)**
Vomiting † 1		

# participants affected / at risk	2/28 (7.14%)	2/26 (7.69%)
Infections and infestations		
Influenza † 1		
# participants affected / at risk	5/28 (17.86%)	7/26 (26.92%)
Metabolism and nutrition disorders		
Hyperglycemia † 1		
# participants affected / at risk	1/28 (3.57%)	5/26 (19.23%)
Nervous system disorders		
Headache † 1		
# participants affected / at risk	5/28 (17.86%)	4/26 (15.38%)
Dizziness † 1		
# participants affected / at risk	1/28 (3.57%)	2/26 (7.69%)
Migraine † 1		
# participants affected / at risk	0/28 (0.00%)	2/26 (7.69%)
Restlessness † 1		
# participants affected / at risk	0/28 (0.00%)	2/26 (7.69%)
Psychiatric disorders		
Depression † 1		
# participants affected / at risk	0/28 (0.00%)	2/26 (7.69%)
Respiratory, thoracic and mediastinal disorders		
Cough † 1		
# participants affected / at risk	2/28 (7.14%)	0/26 (0.00%)
Pharyngolaryngeal pain † 1		
# participants affected / at risk	2/28 (7.14%)	1/26 (3.85%)

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA 11.0

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):

Gill A, Hoogwerf BJ, Burger J, Bruce S, Macconell L, Yan P, Braun D, Giaconia J, Malone J. Effect of exenatide on heart rate and blood pressure in subjects with type 2 diabetes mellitus: a double-blind, placebo-controlled, randomized pilot study. Cardiovasc Diabetol. 2010 Jan 28;9:6. doi: 10.1186/1475-2840-9-6.

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