Trial record **1 of 1** for: gwbo

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An Exploratory Study of the Effect of Treatment Interruption on Safety of Exenatide in Patients With Type 2 Diabetes

ClinicalTrials.gov Identifier: NCT00516048

Recruitment Status: Completed
First Posted: August 14, 2007
Results First Posted: June 17, 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: Non-Randomized; Intervention Model: Parallel Assignment; Masking: None (Open Label); Primary Purpose: Treatment
Condition:	Type 2 Diabetes Mellitus
Intervention:	Drug: exenatide

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
Following a period of treatment interruption of at least 2 months, patients for this study were recruited from among patients who were previously exposed to exenatide for at least 3 months in Amylin/Lilly studies GWAO, GWAP, GWAT, and GWBA.

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:Treatment-Emergent Antibody Negative	5mcg exenatide for 4 weeks, followed by 10mcg exenatide for 20 weeks. Assessed as negative for antibodies to exenatide throughout the study.
Exenatide: Treatment-Emergent Antibody Positive	5mcg exenatide for 4 weeks, followed by 10mcg exenatide for 20 weeks. Assessed as positive for

	antibodies to exenatide at any point in the study.
Enrolled But Withdrew Before Receiving Treatment	No exenatide treatment administered and no post-baseline (post-Week 0) assessment of antibody status was conducted.

Participant Flow: Overall Study

	Exenatide:Treatment-Emergent Antibody Negative	Exenatide: Treatment-Emergent Antibody Positive	Enrolled But Withdrew Before Receiving Treatment
STARTED	15	42	1
COMPLETED	15	40	0
NOT COMPLETED	0	2	1
Death	0	0	1
Subject Decision	0	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
Negative Baseline (Week 0) Antibody Status	

	Patients assessed as negative for antibodies to exenatide at baseline (Week 0).
Positive Baseline (Week 0) Antibody Status	Patients assessed as positive for antibodies to exenatide at baseline (Week 0).
Total	Total of all reporting groups

Baseline Measures

	Negative Baseline (Week 0) Antibody Status	Positive Baseline (Week 0) Antibody Status	Total
Overall Participants Analyzed [Units: Participants]	**50**	**8**	**58**
Age [Units: Participants]			
<=18 years	**0**	**0**	**0**
Between 18 and 65 years	**31**	**8**	**39**
>=65 years	**19**	**0**	**19**
Age [Units: Years] Mean (Standard Deviation)	**60.65 (8.95)**	**49.88 (9.84)**	**59.17 (9.74)**
Gender [Units: Participants]			
Female	**20**	**5**	**25**
Male	**30**	**3**	**33**

Outcome Measures

Hide All Outcome Measures

1. **Primary:**

Treatment-emergent Antibody Status (Maximum Titer Level Experienced) [Time Frame: 24 weeks]

Measure Type	Primary
Measure Title	Treatment-emergent Antibody Status (Maximum Titer Level Experienced)
Measure Description	Patients who experienced specified treatment-emergent antibody status at any point during the study (grouped by maximum titer level experienced)
Time Frame	24 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

Reporting Groups

	Description
Exenatide:Treatment-Emergent Antibody Negative	5mcg exenatide for 4 weeks, followed by 10mcg exenatide for 20 weeks. Assessed as negative for antibodies to exenatide throughout the study.
Exenatide: Treatment-Emergent Antibody Positive	5mcg exenatide for 4 weeks, followed by 10mcg exenatide for 20 weeks. Assessed as positive for antibodies to exenatide at any point in the study.
Enrolled But Withdrew Before Receiving Treatment	No exenatide treatment administered and no post-baseline (post-Week 0) assessment of antibody status was conducted.

Measured Values

	Exenatide:Treatment-Emergent Antibody Negative	Exenatide: Treatment-Emergent Antibody Positive	Enrolled But Withdrew Before Receiving Treatment
Participants Analyzed	**15**	**42**	**1**
Treatment-emergent Antibody Status (Maximum Titer Level Experienced) [Units: Participants]			
Antibody negative	**15**	**0**	**0**
Low titer antibodies	**0**	**25**	**0**
Higher titer antibodies	**0**	**17**	**0**

No statistical analysis provided for Treatment-emergent Antibody Status (Maximum Titer Level Experienced)

2. Primary: Incidence of Potentially Immune-related Treatment-emergent Adverse Events [Time Frame: 24 weeks]

Measure Type	Primary
Measure Title	Incidence of Potentially Immune-related Treatment-emergent Adverse Events
Measure Description	Number of patients experiencing a potentially immune-related treatment-emergent adverse event at any point during the study
Time Frame	24 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

Reporting Groups

	Description
Exenatide:Treatment-Emergent Antibody Negative	5mcg exenatide for 4 weeks, followed by 10mcg exenatide for 20 weeks. Assessed as negative for antibodies to exenatide throughout the study.
Exenatide: Treatment-Emergent Antibody Positive	5mcg exenatide for 4 weeks, followed by 10mcg exenatide for 20 weeks. Assessed as positive for antibodies to exenatide at any point in the study.
Enrolled But Withdrew Before Receiving Treatment	No exenatide treatment administered and no post-baseline (post-Week 0) assessment of antibody status was conducted.

Measured Values

	Exenatide:Treatment-Emergent Antibody Negative	Exenatide: Treatment-Emergent Antibody Positive	Enrolled But Withdrew Before Receiving Treatment
Participants Analyzed	**15**	**42**	**1**
Incidence of Potentially Immune-related Treatment-emergent Adverse Events [Units: Participants]			
Arthralgia	**1**	**0**	**0**
Spinal osteoarthritis	**1**	**0**	**0**
Injection site pruritis	**0**	**2**	**0**
Injection site rash	**0**	**1**	**0**
Rash	**0**	**1**	**0**
Eye allergy	**0**	**1**	**0**

No statistical analysis provided for Incidence of Potentially Immune-related Treatment-emergent

Adverse Events

3. Secondary: Change in Hemoglobin A1c (HbA1c) From Baseline to Endpoint [Time Frame: 24 weeks]

Measure Type	Secondary
Measure Title	Change in Hemoglobin A1c (HbA1c) From Baseline to Endpoint
Measure Description	Change in HbA1c from baseline (Week 0) to endpoint (Week 24) by treatment-emergent antibody status
Time Frame	24 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:Treatment-Emergent Antibody Negative	5mcg exenatide for 4 weeks, followed by 10mcg exenatide for 20 weeks. Assessed as negative for antibodies to exenatide throughout the study.
Exenatide: Treatment-Emergent Antibody Positive	5mcg exenatide for 4 weeks, followed by 10mcg exenatide for 20 weeks. Assessed as positive for antibodies to exenatide at any point in the study.
Enrolled But Withdrew Before Receiving Treatment	No exenatide treatment administered and no post-baseline (post-Week 0) assessment of antibody status was conducted.

Measured Values

	Exenatide:Treatment-Emergent Antibody Negative	Exenatide: Treatment-Emergent Antibody Positive	Enrolled But Withdrew Before Receiving Treatment
Participants Analyzed	**15**	**42**	**1**
Change in Hemoglobin A1c (HbA1c) From Baseline to Endpoint [Units: Percent] Mean (Standard Deviation)			
Baseline HbA1c (Week 0)	**8.13 (0.66)**	**8.05 (1.00)**	**0 (0)**
Change in HbA1c at endpoint (Week 24)	**-1.03 (0.74)**	**-0.30 (0.94)**	**0 (0)**

No statistical analysis provided for Change in Hemoglobin A1c (HbA1c) From Baseline to Endpoint

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Exenatide:Treatment-Emergent Antibody Negative	5mcg exenatide for 4 weeks, followed by 10mcg exenatide for 20 weeks. Assessed as negative for

	antibodies to exenatide throughout the study.
Exenatide: Treatment-Emergent Antibody Positive	5mcg exenatide for 4 weeks, followed by 10mcg exenatide for 20 weeks. Assessed as positive for antibodies to exenatide at any point in the study.
Enrolled But Withdrew Before Receiving Treatment	No exenatide treatment administered and no post-baseline (post-Week 0) assessment of antibody status was conducted.

Serious Adverse Events

	Exenatide:Treatment-Emergent Antibody Negative	Exenatide: Treatment-Emergent Antibody Positive	Enrolled But Withdrew Before Receiving Treatment
Total, Serious Adverse Events			
# participants affected	**0**	**1**	**1**
General disorders			
Sudden death † [1]			
# participants affected / at risk	**0/15 (0.00%)**	**0/42 (0.00%)**	**1/1 (100.00%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hepatic neoplasm malignant † [1]			
# participants affected / at risk	**0/15 (0.00%)**	**1/42 (2.38%)**	**0/1 (0.00%)**

† 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:Treatment-Emergent Antibody Negative	5mcg exenatide for 4 weeks, followed by 10mcg exenatide for 20 weeks. Assessed as negative for antibodies to exenatide throughout the study.
Exenatide: Treatment-Emergent Antibody Positive	5mcg exenatide for 4 weeks, followed by 10mcg exenatide for 20 weeks. Assessed as positive for antibodies to exenatide at any point in the study.
Enrolled But Withdrew Before Receiving Treatment	No exenatide treatment administered and no post-baseline (post-Week 0) assessment of antibody status was conducted.

Other Adverse Events

		Exenatide: Treatment-	**Enrolled But Withdrew**

	Exenatide:Treatment-Emergent Antibody Negative	Emergent Antibody Positive	Before Receiving Treatment
Total, Other (not including serious) Adverse Events			
# participants affected	**7**	**11**	**0**
Gastrointestinal disorders			
Toothache † 1			
# participants affected / at risk	**0/15 (0.00%)**	**2/42 (4.76%)**	**0/1 (0.00%)**
Diarrhoea † 1			
# participants affected / at risk	**1/15 (6.67%)**	**1/42 (2.38%)**	**0/1 (0.00%)**
Gastrooesphageal reflux disease † 1			
# participants affected / at risk	**1/15 (6.67%)**	**0/42 (0.00%)**	**0/1 (0.00%)**
Periodontitis † 1			
# participants affected / at risk	**1/15 (6.67%)**	**0/42 (0.00%)**	**0/1 (0.00%)**
Vomiting † 1			
# participants affected / at risk	**1/15 (6.67%)**	**0/42 (0.00%)**	**0/1 (0.00%)**
General disorders			
Injection site pruritis † 1			
# participants affected / at risk	**0/15 (0.00%)**	**2/42 (4.76%)**	**0/1 (0.00%)**
Infections and infestations			
Nasopharyngitis † 1			
	1/15 (6.67%)	**2/42 (4.76%)**	**0/1 (0.00%)**

# participants affected / at risk			
Influenza † 1			
# participants affected / at risk	**0/15 (0.00%)**	**2/42 (4.76%)**	**0/1 (0.00%)**
Viral infection † 1			
# participants affected / at risk	**0/15 (0.00%)**	**2/42 (4.76%)**	**0/1 (0.00%)**
Otitis externa † 1			
# participants affected / at risk	**1/15 (6.67%)**	**0/42 (0.00%)**	**0/1 (0.00%)**
Otitis media † 1			
# participants affected / at risk	**1/15 (6.67%)**	**0/42 (0.00%)**	**0/1 (0.00%)**
Metabolism and nutrition disorders			
Hyperglycaemia † 1			
# participants affected / at risk	**1/15 (6.67%)**	**0/42 (0.00%)**	**0/1 (0.00%)**
Musculoskeletal and connective tissue disorders			
Arthralgia † 1			
# participants affected / at risk	**1/15 (6.67%)**	**0/42 (0.00%)**	**0/1 (0.00%)**
Spinal osteoarthritis † 1			
# participants affected / at risk	**1/15 (6.67%)**	**0/42 (0.00%)**	**0/1 (0.00%)**

† 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

Responsible Party:	AstraZeneca
ClinicalTrials.gov Identifier:	NCT00516048 History of Changes
Other Study ID Numbers:	H8O-MC-**GWBO**
First Submitted:	August 10, 2007
First Posted:	August 14, 2007
Results First Submitted:	April 29, 2009
Results First Posted:	June 17, 2009
Last Update Posted:	April 7, 2015