https://clinicaltrials.gov/ct2/show/results/NCT02168491?sect=X0123456#all

Feasibility of Once/Daily Administered GLP/1 Receptoragonist (Lixisenatide) in Combination With Basal Insulin (LixiBIT)

This study has been completed.
Sponsor:
Medical University of Vienna
Information provided by (Responsible Party):
Prof. Dr. Michael Krebs, Medical University of Vienna
ClinicalTrials.gov Identifier:
NCT02168491
First received: June 12, 2014
Last updated: March 31, 2017
Last verified: March 2017
History of Changes

Results First Received: December 23, 2016

Study Type:	Interventional
Study Design:	Intervention Model: Single Group Assignment; Masking: None (Open Label); Primary Purpose: Treatment
Condition:	Type 2 Diabetes Mellitus
Interventions:	Drug: Lixisenatide Drug: Insulin glargine

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

11 patients were screened

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
2 patients declined to participate because of time restraints, thus study medication was administered in 9 patients

Reporting Groups

	Description
Lixisenatide With Basal Insulin (LixiBIT)	Type 2 diabetic patients will be included to perform in this study and will be switched from premixed insulin to insulin glargine and lixisenatide Lixisenatide: Patients will be switched to basal insulin glargine (Lantus, once daily in the morning) and GLP-1 receptor agonist Lixisenatide (Lyxumia, once daily in the morning before breakfast; days 1-14 10 µg thereafter 20 µg). The (mean) daily dose of premixed insulin will be calculated based on the records of the run in period. The initial dose of insulin glargine will be adjusted at about 60% of the daily insulin dose of premixed insulin. This is based on the observed reduction of required insulin dose described in recent literature upon initiation with a GLP-1 agonist. Insulin glargine: Patients will be switched to basal insulin glargine (Lantus, once daily in the morning) and GLP-1 receptor agonist Lixisenatide (Lyxumia, once daily in the morning before breakfast; days 1-14 10 µg thereafter 20 µg). The (mean) daily dose of

Participant Flow: Overall Study

	Lixisenatide With Basal Insulin (LixiBIT)
STARTED	9
COMPLETED	8
NOT COMPLETED	1
Withdrawal by Subject	1

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
Lixisenatide With Basal Insulin (LixiBIT)	Type 2 diabetic patients will be included to perform in this study and will be switched from premixed insulin to insulin glargine and lixisenatide

Baseline Measures

	Lixisenatide With Basal Insulin (LixiBIT)	
Overall Participants Analyzed [Units: Participants]	9	
Age [Units: Years] Mean (Standard Deviation)	65.6 (6.0)	
Sex: Female, Male [Units: Participants] Count of Participants		
Female	3	
Male	6	
Race (NIH/OMB) [Units: Participants] Count of Participants		
American Indian or Alaska Native	0	0.0%
Asian	0	0.0%
Native Hawaiian or Other Pacific Islander	0	0.0%
Black or African American	0	0.0%
White	9	100.0%
More than one race	0	0.0%
Unknown or Not Reported	0	0.0%
Region of Enrollment [Units: Participants] Count of Participants		
Austria	9	

Outcome Measures
Hide All Outcome Measures

1. Primary: Change in HbA1c From Baseline to End [Time Frame: 12 weeks]

Measure Type	Primary
Measure Title	Change in HbA1c From Baseline to End
Measure Description	A change between two time points is reported. Time Frame: baseline and 12 weeks.
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.
No text entered.

Reporting Groups

	Description
Lixisenatide With Basal Insulin (LixiBIT)	Type 2 diabetic patients will be included to perform in this study and will be switched from premixed insulin to insulin glargine and lixisenatide

Measured Values

	Lixisenatide With Basal Insulin (LixiBIT)
Participants Analyzed [Units: Participants]	9
Change in HbA1c From Baseline to End [Units: HbA1c in percent] Mean (Standard Deviation)	-0.54 (0.52)

Statistical Analysis 1 for Change in HbA1c From Baseline to End

Groups [1]	Lixisenatide With Basal Insulin (LixiBIT)
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	paired t test
P Value [4]	<0.02

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

No text entered.

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

No text entered.

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

No text entered.

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

No text entered.

2. Secondary: Change in Fasting Plasma Glucose (FPG, Mean Over 2 Weeks) [Time Frame: 12 weeks]

Measure Type	Secondary
Measure Title	Change in Fasting Plasma Glucose (FPG, Mean Over 2 Weeks)
Measure Description	Patients will be instructed to record all insulin injections and a complete 7-point-blood glucose profile (fasting, 2h after breakfast, before lunch, 2h after lunch, before dinner, 2h after dinner, late before going to bed) during a one-week prestudy run-in period to confirm compliance and document current metabolic control and doses of premixed insulin. Patients will be asked to record not only glucose profiles (at least 4 measurements per day) but also the occurrence of hypoglycemic symptoms or other adverse effects daily throughout the study. During the last week of the study patients will be asked to again record a complete 7-point-blood glucose profile (fasting, 2h after breakfast, before lunch, 2h after lunch, before dinner, 2h after dinner, late before going to bed) and drug injections to confirm compliance and document metabolic control.
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.
No text entered.

Reporting Groups

	Description

Lixisenatide With Basal Insulin (LixiBIT)	Type 2 diabetic patients will be included to perform in this study and will be switched from premixed insulin to insulin glargine and lixisenatide

Measured Values

	Lixisenatide With Basal Insulin (LixiBIT)
Participants Analyzed [Units: Participants]	9
Change in Fasting Plasma Glucose (FPG, Mean Over 2 Weeks) [Units: Glucose in mg/dl] Mean (95% Confidence Interval)	-9 (-24.1 to 6.1)

Statistical Analysis 1 for Change in Fasting Plasma Glucose (FPG, Mean Over 2 Weeks)

Groups [1]	Lixisenatide With Basal Insulin (LixiBIT)
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	paired t test
P Value [4]	0.24

[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: Change in Body Weight From Baseline to End of Study [Time Frame: 12 weeks]

Measure Type	Secondary
Measure Title	Change in Body Weight From Baseline to End of Study

Measure Description	A change between two time points is reported. Time Frame: baseline and 12 weeks.
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.
No text entered.

Reporting Groups

	Description
Lixisenatide With Basal Insulin (LixiBIT)	Type 2 diabetic patients will be included to perform in this study and will be switched from premixed insulin to insulin glargine and lixisenatide

Measured Values

	Lixisenatide With Basal Insulin (LixiBIT)
Participants Analyzed [Units: Participants]	9
Change in Body Weight From Baseline to End of Study [Units: Weight in kg] Mean (Standard Deviation)	-1.4 (3.6)

Statistical Analysis 1 for Change in Body Weight From Baseline to End of Study

Groups [1]	Lixisenatide With Basal Insulin (LixiBIT)
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	paired t test
P Value [4]	0.28

[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
Lixisenatide With Basal Insulin (LixiBIT)	Type 2 diabetic patients will be included to perform in this study and will be switched from premixed insulin to insulin glargine and lixisenatide

Serious Adverse Events

	Lixisenatide With Basal Insulin (LixiBIT)
Total, Serious Adverse Events	
# participants affected / at risk	1/9 (11.11%)
Surgical and medical procedures	
elective ENT surgery	
# participants affected / at risk	1/9 (11.11%)
# events	1

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
Lixisenatide With Basal Insulin (LixiBIT)	Type 2 diabetic patients will be included to perform in this study and will be switched from premixed insulin to insulin glargine and lixisenatide

Other Adverse Events

	Lixisenatide With Basal Insulin (LixiBIT)
Total, Other (not including serious) Adverse Events	
# participants affected / at risk	3/9 (33.33%)
Endocrine disorders	
mild asymptomatic hypoglycaemia	
# participants affected / at risk	3/9 (33.33%)
# events	8
symptomatic hypoglycaemia	
# participants affected / at risk	1/9 (11.11%)
# events	1
hypercholesterolaemia	
# participants affected / at risk	2/9 (22.22%)
# events	2
Eye disorders	
elective ambulatory cataract surgery	
# participants affected / at risk	1/9 (11.11%)
# events	1
Gastrointestinal disorders	
mild gastrointestinal complaints	
# participants affected / at risk	2/9 (22.22%)
# events	3
General disorders	
cough	
# participants affected / at risk	1/9 (11.11%)
# events	1
Infections and infestations	
urinary tract infection	
# participants affected / at risk	2/9 (22.22%)
# events	3
Musculoskeletal and connective tissue disorders	
shoulder pain	
# participants affected / at risk	1/9 (11.11%)

# events	1
Renal and urinary disorders	
haematuria	
# participants affected / at risk	1/9 (11.11%)
# events	1

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.

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