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Clobazam in Patients With Lennox-Gastaut Syndrome

This study has been completed.

Sponsor:
Lundbeck LLC

Information provided by (Responsible Party):
Lundbeck LLC

ClinicalTrials.gov Identifier:
NCT00518713

First received: August 20, 2007
Last updated: January 6, 2012
Last verified: January 2012
History of Changes

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Results First Received: November 7, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator); Primary Purpose: Treatment
Conditions:	Epilepsy Epilepsy, Generalized Seizures
Interventions:	Drug: Clobazam Low Dose Drug: Clobazam Medium Dose Drug: Clobazam High Dose 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
Clobazam Low Dose	0.25 mg/kg/day; tablets; orally; for 15-18 weeks
Clobazam Medium Dose	0.5 mg/kg/day; tablets; orally; for 15-18 weeks
Clobazam High Dose	1.0 mg/kg/day; tablets; orally; for 15-18 weeks
Placebo	tablets; orally; daily for 15-18 weeks

Participant Flow: Overall Study

	Clobazam Low Dose	Clobazam Medium Dose	Clobazam High Dose	Placebo
STARTED	**58**	**62**	**59**	**59**
Modified Intent-to-Treat Population	**53**	**58**	**49**	**57**
COMPLETED	**50**	**45**	**41**	**41**
NOT COMPLETED	**8**	**17**	**18**	**18**

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
Clobazam Low Dose	0.25 mg/kg/day; tablets; orally; for 15-18 weeks
Clobazam Medium Dose	0.5 mg/kg/day; tablets; orally; for 15-18 weeks
Clobazam High Dose	1.0 mg/kg/day; tablets; orally; for 15-18 weeks
Placebo	tablets; orally; daily for 15-18 weeks
Total	Total of all reporting groups

Baseline Measures

	Clobazam Low Dose	Clobazam Medium Dose	Clobazam High Dose	Placebo	Total
Overall Participants [units: participants]	**58**	**62**	**59**	**59**	**238**
Age [units: participants]					
<=18 years	**48**	**48**	**49**	**48**	**193**
Between 18 and 65 years	**10**	**14**	**10**	**11**	**45**
>=65 years	**0**	**0**	**0**	**0**	**0**
Age [units: years] Mean (Standard Deviation)	**10.9 (7.24)**	**14.1 (10.42)**	**11.7 (8.48)**	**13.0 (9.17)**	**12.4 (8.96)**

Gender [units: participants]					
Female	**22**	**26**	**25**	**21**	**94**
Male	**36**	**36**	**34**	**38**	**144**

Outcome Measures

Hide All Outcome Measures

1. Primary: Percent Reduction in Number of Drop Seizures (12-week Maintenance Period). [Time Frame: 4-week baseline period and 12-week maintenance period]

Measure Type	Primary
Measure Title	Percent Reduction in Number of Drop Seizures (12-week Maintenance Period).
Measure Description	Number of drop seizures (average per week) was obtained from seizure diaries. The average drop in seizures per week for patients who did not complete the maintenance period was calculated based on the time from the beginning of the maintenance period to date of withdrawal.
Time Frame	4-week baseline period and 12-week maintenance period
Safety Issue	No

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.
Modified Intent-to-Treat (MITT) population

Reporting Groups

	Description
Clobazam Low Dose	0.25 mg/kg/day; tablets; orally; for 15-18 weeks
Clobazam Medium Dose	0.5 mg/kg/day; tablets; orally; for 15-18 weeks
Clobazam High Dose	1.0 mg/kg/day; tablets; orally; for 15-18 weeks
Placebo	tablets; orally; daily for 15-18 weeks

Measured Values

	Clobazam Low Dose	**Clobazam Medium Dose**	**Clobazam High Dose**	**Placebo**
Overall Participants [units: participants]	**53**	**58**	**49**	**57**
Percent Reduction in Number of Drop Seizures (12-week Maintenance Period). [units: Percent Reduction] Least Squares Mean (Full Range)	**41.2 (-119 to 100)**	**49.4 (-262 to 100)**	**68.3 (-39 to 100)**	**12.1 (-374 to 100)**

Statistical Analysis 1 for Percent Reduction in Number of Drop Seizures (12-week Maintenance Period).

Groups [1]	Clobazam Low Dose vs. Placebo
Method [2]	ANCOVA

P Value [3]	0.0120

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Analysis of covariance (ANCOVA) with the percent reduction in drop seizures as the dependent variable and treatment, pooled center, and baseline drop seizure rate as the independent variables. A step-down procedure used, starting with the high dose versus placebo.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	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 Percent Reduction in Number of Drop Seizures (12-week Maintenance Period).

Groups [1]	Clobazam Medium Dose vs. Placebo
Method [2]	ANCOVA
P Value [3]	0.0015

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	ANCOVA with the percent reduction in drop seizures as the dependent variable and treatment, pooled center, and baseline drop seizure rate as the independent variables. A step-down procedure used, starting with the high dose versus placebo.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	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 3 for Percent Reduction in Number of Drop Seizures (12-week Maintenance Period).

Groups [1]	Clobazam High Dose vs. Placebo
Method [2]	ANCOVA
P Value [3]	<0.0001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	ANCOVA with the percent reduction in drop seizures as the dependent variable and treatment, pooled center, and baseline drop seizure rate as the independent variables. A step-down procedure used, starting with the high dose versus placebo.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	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: Percent Reduction in Number of Drop Seizures (First 4 Weeks of the 12-week Maintenance Period). [Time Frame: 4-week

baseline period and the first 4 weeks of the 12-week maintenance period]

Measure Type	Secondary
Measure Title	Percent Reduction in Number of Drop Seizures (First 4 Weeks of the 12-week Maintenance Period).
Measure Description	Number of drop seizures (average per week) was obtained from seizure diaries. The average drop in seizures per week for patients who did not complete the maintenance period was calculated based on the time from the beginning of the maintenance period to date of withdrawal.
Time Frame	4-week baseline period and the first 4 weeks of the 12-week maintenance period
Safety Issue	No

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.
MITT population

Reporting Groups

	Description
Clobazam Low Dose	0.25 mg/kg/day; tablets; orally; for 15-18 weeks
Clobazam Medium Dose	0.5 mg/kg/day; tablets; orally; for 15-18 weeks
Clobazam High Dose	1.0 mg/kg/day; tablets; orally; for 15-18 weeks
Placebo	tablets; orally; daily for 15-18 weeks

Measured Values

	Clobazam Low Dose	**Clobazam Medium Dose**	**Clobazam High Dose**	**Placebo**
Overall Participants [units: participants]	**53**	**58**	**49**	**57**
Percent Reduction in Number of Drop Seizures (First 4 Weeks of the 12-week Maintenance Period). [units: Percent reduction] Least Squares Mean (Full Range)	**47.8 (-103 to 100)**	**58.9 (-147 to 100)**	**71.0 (-58 to 100)**	**18.6 (-106 to 100)**

Statistical Analysis 1 for Percent Reduction in Number of Drop Seizures (First 4 Weeks of the 12-week Maintenance Period).

Groups [1]	Clobazam Low Dose vs. Placebo
Method [2]	ANCOVA
P Value [3]	0.0027

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	ANCOVA with the percent reduction in drop seizures as the dependent variable and treatment, pooled center, and baseline drop seizure rate as the independent variables. A step-down procedure used, starting with the high dose versus placebo.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	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 Percent Reduction in Number of Drop Seizures (First 4 Weeks of the 12-week Maintenance Period).

Groups [1]	Clobazam Medium Dose vs. Placebo
Method [2]	ANCOVA
P Value [3]	<0.0001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	ANCOVA with the percent reduction in drop seizures as the dependent variable and treatment, pooled center, and baseline drop seizure rate as the independent variables. A step-down procedure used, starting with the high dose versus placebo.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	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 3 for Percent Reduction in Number of Drop Seizures (First 4 Weeks of the 12-week Maintenance Period).

Groups [1]	Clobazam High Dose vs. Placebo
Method [2]	ANCOVA
P Value [3]	<0.0001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	ANCOVA with the percent reduction in drop seizures as the dependent variable and treatment, pooled center, and baseline drop seizure rate as the independent variables. A step-down procedure used, starting with the high dose versus placebo.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	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: Percent Reduction in Number of Drop Seizures (Middle 4 Weeks of the 12-week Maintenance Period). [Time Frame: 4-week baseline period and the middle 4 weeks of the 12-week maintenance period]

Measure Type	Secondary
Measure Title	Percent Reduction in Number of Drop Seizures (Middle 4 Weeks of the 12-week Maintenance Period).
Measure Description	Number of drop seizures (average per week) was obtained from seizure diaries. The average drop in seizures per week for patients who did not complete the maintenance period was calculated based on the time from the beginning of the maintenance period to date of withdrawal.
Time Frame	4-week baseline period and the middle 4 weeks of the 12-week maintenance period
Safety Issue	No

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
Clobazam Low Dose	0.25 mg/kg/day; tablets; orally; for 15-18 weeks
Clobazam Medium Dose	0.5 mg/kg/day; tablets; orally; for 15-18 weeks
Clobazam High Dose	1.0 mg/kg/day; tablets; orally; for 15-18 weeks
Placebo	tablets; orally; daily for 15-18 weeks

Measured Values

	Clobazam Low Dose	**Clobazam Medium Dose**	**Clobazam High Dose**	**Placebo**
Overall Participants [units: participants]	**52**	**53**	**44**	**47**
Percent Reduction in Number of Drop Seizures (Middle 4 Weeks of the 12-week Maintenance Period). [units: Percent reduction] Least Squares Mean (Full Range)	**44.1** **(-36 to 100)**	**38.8** **(-433 to 100)**	**64.9** **(-125 to 100)**	**21.1** **(-284 to 100)**

Statistical Analysis 1 for Percent Reduction in Number of Drop Seizures (Middle 4 Weeks of the 12-week Maintenance Period).

Groups [1]	Clobazam Low Dose vs. Placebo
Method [2]	ANCOVA
P Value [3]	0.1041

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	ANCOVA with the percent reduction in drop seizures as the dependent variable and treatment, pooled center, and baseline drop seizure rate as the independent variables. A step-down procedure used, starting with the high dose versus placebo.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	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 Percent Reduction in Number of Drop Seizures (Middle 4 Weeks of the 12-week Maintenance Period).

Groups [1]	Clobazam Medium Dose vs. Placebo
Method [2]	ANCOVA
P Value [3]	0.2207

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	ANCOVA with the percent reduction in drop seizures as the dependent variable and treatment, pooled center, and baseline drop

	seizure rate as the independent variables. A step-down procedure used, starting with the high dose versus placebo.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	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 3 for Percent Reduction in Number of Drop Seizures (Middle 4 Weeks of the 12-week Maintenance Period).

Groups [1]	Clobazam High Dose vs. Placebo
Method [2]	ANCOVA
P Value [3]	0.0025

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	ANCOVA with the percent reduction in drop seizures as the dependent variable and treatment, pooled center, and baseline drop seizure rate as the independent variables. A step-down procedure used, starting with the high dose versus placebo.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	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: Percent Reduction in Number of Drop Seizures (Last 4 Weeks of the 12-week Maintenance Period). [Time Frame: 4-week baseline period and the last 4 weeks of the 12-week maintenance period]

Measure Type	Secondary
Measure Title	Percent Reduction in Number of Drop Seizures (Last 4 Weeks of the 12-week Maintenance Period).
Measure Description	Number of drop seizures (average per week) was obtained from seizure diaries. The average drop in seizures per week for patients who did not complete the maintenance period was calculated based on the time from the beginning of the maintenance period to date of withdrawal.
Time Frame	4-week baseline period and the last 4 weeks of the 12-week maintenance period
Safety Issue	No

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
Clobazam Low Dose	0.25 mg/kg/day; tablets; orally; for 15-18 weeks
Clobazam Medium Dose	0.5 mg/kg/day; tablets; orally; for 15-18 weeks
Clobazam High Dose	

	1.0 mg/kg/day; tablets; orally; for 15-18 weeks
Placebo	tablets; orally; daily for 15-18 weeks

Measured Values

	Clobazam Low Dose	Clobazam Medium Dose	Clobazam High Dose	Placebo
Overall Participants [units: participants]	**51**	**46**	**42**	**44**
Percent Reduction in Number of Drop Seizures (Last 4 Weeks of the 12-week Maintenance Period). [units: Percent reduction] Least Squares Mean (Full Range)	**31.8** **(-477 to 100)**	**56.0** **(-228 to 100)**	**68.0** **(-117 to 100)**	**-0.1** **(-948 to 100)**

Statistical Analysis 1 for Percent Reduction in Number of Drop Seizures (Last 4 Weeks of the 12-week Maintenance Period).

Groups [1]	Clobazam Low Dose vs. Placebo
Method [2]	ANCOVA
P Value [3]	0.1469

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	ANCOVA with the percent reduction in drop seizures as the dependent variable and treatment, pooled center, and baseline drop seizure rate as the independent variables. A step-down procedure used, starting with the high dose versus placebo.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	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 Percent Reduction in Number of Drop Seizures (Last 4 Weeks of the 12-week Maintenance Period).

Groups [1]	Clobazam Medium Dose vs. Placebo
Method [2]	ANCOVA
P Value [3]	0.0161

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	ANCOVA with the percent reduction in drop seizures as the dependent variable and treatment, pooled center, and baseline drop seizure rate as the independent variables. A step-down procedure used, starting with the high dose versus placebo.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	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 3 for Percent Reduction in Number of Drop Seizures (Last 4 Weeks of the 12-week Maintenance Period).

[1]	Clobazam High Dose vs. Placebo

Groups	
Method [2]	ANCOVA
P Value [3]	0.0024

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	ANCOVA with the percent reduction in drop seizures as the dependent variable and treatment, pooled center, and baseline drop seizure rate as the independent variables. A step-down procedure used, starting with the high dose versus placebo.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	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: Percent of Patients Considered Treatment Responders Defined as Those With a >=25%, >=50%, >=75%, 100% Reduction in Drop Seizures (12-week Maintenance Period). [Time Frame: 4-week baseline period and the 12-week maintenance period]

Measure Type	Secondary
Measure Title	Percent of Patients Considered Treatment Responders Defined as Those With a >=25%, >=50%, >=75%, 100% Reduction in Drop Seizures (12-week Maintenance Period).
Measure Description	Number of drop seizures (average per week) was obtained from seizure diaries. The average drop in seizures per week for patients who did not complete the maintenance period was calculated based on the time from the beginning of the maintenance period to date of withdrawal.
Time Frame	4-week baseline period and the 12-week maintenance period
Safety Issue	No

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
Clobazam Low Dose	0.25 mg/kg/day; tablets; orally; for 15-18 weeks
Clobazam Medium Dose	0.5 mg/kg/day; tablets; orally; for 15-18 weeks
Clobazam High Dose	1.0 mg/kg/day; tablets; orally; for 15-18 weeks
Placebo	tablets; orally; daily for 15-18 weeks

Measured Values

	Clobazam Low Dose	**Clobazam Medium Dose**	**Clobazam High Dose**	**Placebo**
Overall Participants [units: participants]	**53**	**58**	**49**	**57**

Percent of Patients Considered Treatment Responders Defined as Those With a >=25%, >=50%, >=75%, 100% Reduction in Drop Seizures (12-week Maintenance Period). [units: Percent of responders]				
≥ 25% reduction	**34**	**46**	**41**	**28**
≥ 50% reduction	**23**	**34**	**38**	**18**
≥ 75% reduction	**15**	**22**	**31**	**6**
100% reduction	**4**	**7**	**12**	**2**

Statistical Analysis 1 for Percent of Patients Considered Treatment Responders Defined as Those With a >=25%, >=50%, >=75%, 100% Reduction in Drop Seizures (12-week Maintenance Period).

Groups [1]	Clobazam Low Dose vs. Placebo
Method [2]	ANCOVA
P Value [3]	0.1324

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	≥ 25% reduction. ANCOVA with the percent reduction in drop seizures as the dependent variable and treatment, pooled center, and baseline drop seizure rate as the independent variables. A step-down procedure used, starting with the high dose versus placebo.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	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 Percent of Patients Considered Treatment Responders Defined as Those With a >=25%, >=50%, >=75%, 100% Reduction in Drop Seizures (12-week Maintenance Period).

Groups [1]	Clobazam Medium Dose vs. Placebo
Method [2]	ANCOVA
P Value [3]	0.0026

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	≥ 25% reduction. ANCOVA with the percent reduction in drop seizures as the dependent variable and treatment, pooled center, and baseline drop seizure rate as the independent variables. A step-down procedure used, starting with the high dose versus placebo.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	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 3 for Percent of Patients Considered Treatment Responders Defined as Those With a >=25%, >=50%, >=75%, 100% Reduction in Drop Seizures (12-week Maintenance Period).

Groups [1]	Clobazam High Dose vs. Placebo
Method [2]	ANCOVA
[3]	

P Value	0.0004

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	≥ 25% reduction. ANCOVA with the percent reduction in drop seizures as the dependent variable and treatment, pooled center, and baseline drop seizure rate as the independent variables. A step-down procedure used, starting with the high dose versus placebo.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	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 4 for Percent of Patients Considered Treatment Responders Defined as Those With a >=25%, >=50%, >=75%, 100% Reduction in Drop Seizures (12-week Maintenance Period).

Groups [1]	Clobazam Low Dose vs. Placebo
Method [2]	ANCOVA
P Value [3]	0.3383

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	≥ 50% reduction. ANCOVA with the percent reduction in drop seizures as the dependent variable and treatment, pooled center, and baseline drop seizure rate as the independent variables. A step-down procedure used, starting with the high dose versus placebo.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	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 5 for Percent of Patients Considered Treatment Responders Defined as Those With a >=25%, >=50%, >=75%, 100% Reduction in Drop Seizures (12-week Maintenance Period).

Groups [1]	Clobazam Medium Dose vs. Placebo
Method [2]	ANCOVA
P Value [3]	0.0159

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	≥ 50% reduction. ANCOVA with the percent reduction in drop seizures as the dependent variable and treatment, pooled center, and baseline drop seizure rate as the independent variables. A step-down procedure used, starting with the high dose versus placebo.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	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 6 for Percent of Patients Considered Treatment Responders Defined as Those With a >=25%, >=50%, >=75%, 100% Reduction in Drop Seizures (12-week Maintenance Period).

Groups [1]	Clobazam High Dose vs. Placebo
Method [2]	ANCOVA
P Value [3]	<0.0001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	≥ 50% reduction. ANCOVA with the percent reduction in drop seizures as the dependent variable and treatment, pooled center, and baseline drop seizure rate as the independent variables. A step-down procedure used, starting with the high dose versus placebo.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	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 7 for Percent of Patients Considered Treatment Responders Defined as Those With a >=25%, >=50%, >=75%, 100% Reduction in Drop Seizures (12-week Maintenance Period).

Groups [1]	Clobazam Low Dose vs. Placebo
Method [2]	ANCOVA
P Value [3]	0.0279

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	≥ 75% reduction. ANCOVA with the percent reduction in drop seizures as the dependent variable and treatment, pooled center, and baseline drop seizure rate as the independent variables. A step-down procedure used, starting with the high dose versus placebo.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	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 8 for Percent of Patients Considered Treatment Responders Defined as Those With a >=25%, >=50%, >=75%, 100% Reduction in Drop Seizures (12-week Maintenance Period).

Groups [1]	Clobazam Medium Dose vs. Placebo
Method [2]	ANCOVA
P Value [3]	0.0010

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	≥ 75% reduction. ANCOVA with the percent reduction in drop seizures as the dependent variable and treatment, pooled center, and baseline drop seizure rate as the independent variables. A step-down procedure used, starting with the high dose versus placebo.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	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 9 for Percent of Patients Considered Treatment Responders Defined as Those With a >=25%, >=50%, >=75%, 100% Reduction in Drop Seizures (12-week Maintenance Period).

Groups [1]	Clobazam High Dose vs. Placebo
Method [2]	ANCOVA
P Value [3]	<0.0001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	≥ 75% reduction. ANCOVA with the percent reduction in drop seizures as the dependent variable and treatment, pooled center, and baseline drop seizure rate as the independent variables. A step-down procedure used, starting with the high dose versus placebo.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	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: Percent of Patients Considered Treatment Responders Defined as Those With a >=25%, >=50%, >=75%, 100% Reduction in Drop Seizures (First 4 Weeks of the 12-week Maintenance Period). [Time Frame: 4-week baseline period and the first 4 weeks of the 12-week maintenance period]

Measure Type	Secondary
Measure Title	Percent of Patients Considered Treatment Responders Defined as Those With a >=25%, >=50%, >=75%, 100% Reduction in Drop Seizures (First 4 Weeks of the 12-week Maintenance Period).
Measure Description	Number of drop seizures (average per week) was obtained from seizure diaries. The average drop in seizures per week for patients who did not complete the maintenance period was calculated based on the time from the beginning of the maintenance period to date of withdrawal.
Time Frame	4-week baseline period and the first 4 weeks of the 12-week maintenance period
Safety Issue	No

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.
MITT

Reporting Groups

	Description
Clobazam Low Dose	0.25 mg/kg/day; tablets; orally; for 15-18 weeks
Clobazam Medium Dose	0.5 mg/kg/day; tablets; orally; for 15-18 weeks
Clobazam High Dose	1.0 mg/kg/day; tablets; orally; for 15-18 weeks
Placebo	tablets; orally; daily for 15-18 weeks

Measured Values

		Clobazam		

	Clobazam Low Dose	Medium Dose	Clobazam High Dose	Placebo
Overall Participants [units: participants]	**53**	**58**	**49**	**57**
Percent of Patients Considered Treatment Responders Defined as Those With a >=25%, >=50%, >=75%, 100% Reduction in Drop Seizures (First 4 Weeks of the 12-week Maintenance Period). [units: Percent of responders]				
≥ 25% reduction	**71.7**	**82.8**	**89.8**	**52.6**
≥ 50% reduction	**47.2**	**72.4**	**77.6**	**31.6**
≥ 75% reduction	**35.8**	**44.8**	**63.3**	**14.0**
100% reduction	**13.2**	**19.0**	**30.6**	**3.5**

No statistical analysis provided for Percent of Patients Considered Treatment Responders Defined as Those With a >=25%, >=50%, >=75%, 100% Reduction in Drop Seizures (First 4 Weeks of the 12-week Maintenance Period).

7. Secondary: Percent of Patients Considered Treatment Responders Defined as Those With a >=25%, >=50%, >=75%, 100% Reduction in Drop Seizures (Middle 4 Weeks of the 12-week Maintenance Period). [Time Frame: 4-week baseline period and the middle 4 weeks of the 12-week maintenance period]

Measure Type	Secondary
Measure Title	Percent of Patients Considered Treatment Responders Defined as Those With a >=25%, >=50%, >=75%, 100% Reduction in Drop Seizures (Middle 4 Weeks of the 12-week Maintenance Period).
Measure Description	Number of drop seizures (average per week) was obtained from seizure diaries. The average drop in seizures per week for patients who did not complete the maintenance period was calculated based on the time from the beginning of the maintenance period to date of withdrawal.
Time Frame	4-week baseline period and the middle 4 weeks of the 12-week maintenance period
Safety Issue	No

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
Clobazam Low Dose	0.25 mg/kg/day; tablets; orally; for 15-18 weeks
Clobazam Medium Dose	0.5 mg/kg/day; tablets; orally; for 15-18 weeks
Clobazam High Dose	1.0 mg/kg/day; tablets; orally; for 15-18 weeks
Placebo	tablets; orally; daily for 15-18 weeks

Measured Values

	Clobazam Low Dose	Clobazam Medium Dose	Clobazam High Dose	Placebo
Overall Participants [units: participants]	**53**	**58**	**49**	**57**

Percent of Patients Considered Treatment Responders Defined as Those With a >=25%, >=50%, >=75%, 100% Reduction in Drop Seizures (Middle 4 Weeks of the 12-week Maintenance Period). [units: Percent Responders]				
≥ 25% reduction	**64.2**	**65.5**	**75.5**	**50.9**
≥ 50% reduction	**43.4**	**51.7**	**71.4**	**24.6**
≥ 75% reduction	**28.3**	**34.5**	**59.2**	**12.3**
100% reduction	**9.4**	**15.5**	**26.5**	**5.3**

No statistical analysis provided for Percent of Patients Considered Treatment Responders Defined as Those With a >=25%, >=50%, >=75%, 100% Reduction in Drop Seizures (Middle 4 Weeks of the 12-week Maintenance Period).

8. Secondary: Percent of Patients Considered Treatment Responders Defined as Those With a >=25%, >=50%, >=75%, 100% Reduction in Drop Seizures (Last 4 Weeks of the 12-week Maintenance Period). [Time Frame: 4-week baseline period and the last 4 weeks of the 12-week maintenance period]

Measure Type	Secondary
Measure Title	Percent of Patients Considered Treatment Responders Defined as Those With a >=25%, >=50%, >=75%, 100% Reduction in Drop Seizures (Last 4 Weeks of the 12-week Maintenance Period).
Measure Description	Number of drop seizures (average per week) was obtained from seizure diaries. The average drop in seizures per week for patients who did not complete the maintenance period was calculated based on the time from the beginning of the maintenance period to date of withdrawal.
Time Frame	4-week baseline period and the last 4 weeks of the 12-week maintenance period
Safety Issue	No

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
Clobazam Low Dose	0.25 mg/kg/day; tablets; orally; for 15-18 weeks
Clobazam Medium Dose	0.5 mg/kg/day; tablets; orally; for 15-18 weeks
Clobazam High Dose	1.0 mg/kg/day; tablets; orally; for 15-18 weeks
Placebo	tablets; orally; daily for 15-18 weeks

Measured Values

	Clobazam Low Dose	**Clobazam Medium Dose**	**Clobazam High Dose**	**Placebo**
Overall Participants [units: participants]	**53**	**58**	**49**	**57**
Percent of Patients Considered Treatment Responders Defined as Those With a >=25%, >=50%, >=75%, 100% Reduction in Drop Seizures (Last 4 Weeks of the 12-week Maintenance Period).				

[units: Percent Responders]				
≥ 25% reduction	**66.0**	**60.3**	**71.4**	**43.9**
≥ 50% reduction	**45.3**	**50.0**	**67.3**	**29.8**
≥ 75% reduction	**28.3**	**36.2**	**57.1**	**12.3**
100% reduction	**13.2**	**15.5**	**20.4**	**5.3**

No statistical analysis provided for Percent of Patients Considered Treatment Responders Defined as Those With a >=25%, >=50%, >=75%, 100% Reduction in Drop Seizures (Last 4 Weeks of the 12-week Maintenance Period).

9. Secondary: Tolerance [Time Frame: 4-week baseline period and first 4/first 8 weeks of the maintenance period]

Measure Type	Secondary
Measure Title	Tolerance
Measure Description	Study responders who have ≥50% reduction in their drop seizure rate during the first 4 or first 8 weeks of maintenance compared to the 4 week baseline period.
Time Frame	4-week baseline period and first 4/first 8 weeks of the maintenance period
Safety Issue	Yes

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.
MITT

Reporting Groups

	Description
Clobazam Low Dose	0.25 mg/kg/day; tablets; orally; for 15-18 weeks
Clobazam Medium Dose	0.5 mg/kg/day; tablets; orally; for 15-18 weeks
Clobazam High Dose	1.0 mg/kg/day; tablets; orally; for 15-18 weeks
Placebo	tablets; orally; daily for 15-18 weeks

Measured Values

	Clobazam Low Dose	**Clobazam Medium Dose**	**Clobazam High Dose**	**Placebo**
Overall Participants [units: participants]	**53**	**58**	**49**	**57**
Tolerance [units: Participants]				
≥ 50% reduction - first 4 weeks of maintenance	**25**	**42**	**38**	**18**
≥ 50% reduction - first 8 weeks of maintenance	**23**	**38**	**38**	**20**

No statistical analysis provided for Tolerance

10. Secondary: Investigator Global Evaluations of the Patient's Overall Change in Symptoms. [Time Frame: Week 15]

Measure Type	

	Secondary
Measure Title	Investigator Global Evaluations of the Patient's Overall Change in Symptoms.
Measure Description	The physician was asked to rate the patient's overall change in symptoms and overall change in seizure activity and Quality of Life since the beginning of clobazam treatment by checking "very much improved", "much improved", "minimally improved", "no change", "minimally worse", "much worse", or "very much worse".
Time Frame	Week 15
Safety Issue	No

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.
Those patients in the MITT population who completed a Physician Global Evaluation at Week 15.

Reporting Groups

	Description
Clobazam Low Dose	0.25 mg/kg/day; tablets; orally; for 15-18 weeks
Clobazam Medium Dose	0.5 mg/kg/day; tablets; orally; for 15-18 weeks
Clobazam High Dose	1.0 mg/kg/day; tablets; orally; for 15-18 weeks
Placebo	tablets; orally; daily for 15-18 weeks

Measured Values

	Clobazam Low Dose	**Clobazam Medium Dose**	**Clobazam High Dose**	**Placebo**
Overall Participants [units: participants]	**52**	**57**	**49**	**55**
Investigator Global Evaluations of the Patient's Overall Change in Symptoms. [units: participants]				
Very much improved	**4**	**10**	**8**	**3**
Much improved	**20**	**27**	**23**	**10**
Minimally improved	**13**	**9**	**8**	**13**
No change	**12**	**9**	**6**	**22**
Minimally worse	**2**	**2**	**3**	**6**
Much worse	**1**	**0**	**1**	**1**
Very much worse	**0**	**0**	**0**	**0**

No statistical analysis provided for Investigator Global Evaluations of the Patient's Overall Change in Symptoms.

11. Secondary: Parent/Caregiver Global Evaluations of the Patient’s Overall Change in Symptoms. [Time Frame: Week 15]

Measure Type	Secondary
Measure Title	Parent/Caregiver Global Evaluations of the Patient’s Overall Change in Symptoms.
Measure Description	The parent/caregiver was asked to rate the patient's overall change in symptoms and overall change in seizure activity and Quality of Life since the beginning of clobazam treatment by checking "very much improved", "much improved", "minimally improved", "no change", "minimally worse", "much worse", or "very much worse".

Time Frame	Week 15
Safety Issue	No

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.
Those patients in the MITT population who had a baseline and Week 15 parent/caregiver global evaluations were analyzed.

Reporting Groups

	Description
Clobazam Low Dose	0.25 mg/kg/day; tablets; orally; for 15-18 weeks
Clobazam Medium Dose	0.5 mg/kg/day; tablets; orally; for 15-18 weeks
Clobazam High Dose	1.0 mg/kg/day; tablets; orally; for 15-18 weeks
Placebo	tablets; orally; daily for 15-18 weeks

Measured Values

	Clobazam Low Dose	**Clobazam Medium Dose**	**Clobazam High Dose**	**Placebo**
Overall Participants [units: participants]	**53**	**57**	**49**	**55**
Parent/Caregiver Global Evaluations of the Patient's Overall Change in Symptoms. [units: participants]				
Very much improved	**8**	**13**	**11**	**4**
Much improved	**14**	**19**	**18**	**10**
Minimally improved	**20**	**14**	**11**	**11**
No change	**8**	**7**	**4**	**21**
Minimally worse	**2**	**2**	**3**	**6**
Much worse	**0**	**2**	**2**	**3**
Very much worse	**1**	**0**	**0**	**0**

No statistical analysis provided for Parent/Caregiver Global Evaluations of the Patient's Overall Change in Symptoms.

12. Other Pre-specified: Percent Reduction in the Number of Non-drop Seizures. [Time Frame: 4-week baseline period and the 12-week maintenance period]

Measure Type	Other Pre-specified
Measure Title	Percent Reduction in the Number of Non-drop Seizures.
Measure Description	This outcome measure evaluated the percent reduction (average per week) in non-drop Seizures. Non-drop seizures were other seizures not meeting the drop seizure definition. Drop seizures were defined as a drop attack or spell (atonic, tonic or myoclonic) involving the entire body, trunk, or head that led to a fall, injury, slumping in chair, or head hitting surface or that could have led to a fall or injury, depending on the position of the patient at the time of the attack or spell.
Time Frame	4-week baseline period and the 12-week maintenance period
Safety Issue	No

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
Clobazam Low Dose	0.25 mg/kg/day; tablets; orally; for 15-18 weeks
Clobazam Medium Dose	0.5 mg/kg/day; tablets; orally; for 15-18 weeks
Clobazam High Dose	1.0 mg/kg/day; tablets; orally; for 15-18 weeks
Placebo	tablets; orally; daily for 15-18 weeks

Measured Values

	Clobazam Low Dose	**Clobazam Medium Dose**	**Clobazam High Dose**	**Placebo**
Overall Participants [units: participants]	**53**	**58**	**49**	**57**
Percent Reduction in the Number of Non-drop Seizures. [units: Percent reduction] Least Squares Mean (Full Range)	**-53.3 (-1627 to 100)**	**-3.3 (-1591 to 100)**	**40.0 (-190 to 100)**	**-76.3 (-1477 to 97)**

Statistical Analysis 1 for Percent Reduction in the Number of Non-drop Seizures.

Groups [1]	Clobazam Low Dose vs. Placebo
Method [2]	ANCOVA
P Value [3]	0.7210

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	ANCOVA with the percent reduction in drop seizures as the dependent variable and treatment, pooled center, and baseline drop seizure rate as the independent variables. A step-down procedure used, starting with the high dose versus placebo.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	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 Percent Reduction in the Number of Non-drop Seizures.

Groups [1]	Clobazam Medium Dose vs. Placebo
Method [2]	ANCOVA
P Value [3]	0.2505

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

	ANCOVA with the percent reduction in drop seizures as the dependent variable and treatment, pooled center, and baseline drop seizure rate as the independent variables. A step-down procedure used, starting with the high dose versus placebo.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	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 3 for Percent Reduction in the Number of Non-drop Seizures.

Groups [1]	Clobazam High Dose vs. Placebo
Method [2]	ANCOVA
P Value [3]	0.0924

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	ANCOVA with the percent reduction in drop seizures as the dependent variable and treatment, pooled center, and baseline drop seizure rate as the independent variables. A step-down procedure used, starting with the high dose versus placebo.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	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. Other Pre-specified: Percent Reduction of Total (Drop and Non-Drop) Seizures. [Time Frame: 4-week baseline period and 12-week maintenance period]

Measure Type	Other Pre-specified
Measure Title	Percent Reduction of Total (Drop and Non-Drop) Seizures.
Measure Description	This outcome measure evaluated the percent reduction in average weekly rate in total (drop and non-drop) seizures. Drop seizures were defined as a drop attack or spell (atonic, tonic or myoclonic) involving the entire body, trunk, or head that led to a fall, injury, slumping in chair, or head hitting surface or that could have led to a fall or injury, depending on the position of the patient at the time of the attack or spell. Non-drop seizures were other seizures not meeting the drop seizure definition.
Time Frame	4-week baseline period and 12-week maintenance period
Safety Issue	No

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
Clobazam Low Dose	0.25 mg/kg/day; tablets; orally; for 15-18 weeks

Clobazam Medium Dose	0.5 mg/kg/day; tablets; orally; for 15-18 weeks
Clobazam High Dose	1.0 mg/kg/day; tablets; orally; for 15-18 weeks
Placebo	tablets; orally; daily for 15-18 weeks

Measured Values

	Clobazam Low Dose	Clobazam Medium Dose	Clobazam High Dose	Placebo
Overall Participants [units: participants]	**53**	**58**	**49**	**57**
Percent Reduction of Total (Drop and Non-Drop) Seizures. [units: Percent reduction] Least Squares Mean (Full Range)	**34.8** **(-155 to 100)**	**45.3** **(-523 to 100)**	**65.3** **(-49 to 100)**	**9.3** **(-189 to 100)**

Statistical Analysis 1 for Percent Reduction of Total (Drop and Non-Drop) Seizures.

Groups [1]	Clobazam Low Dose vs. Placebo
Method [2]	ANCOVA
P Value [3]	0.0414

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	ANCOVA with the percent reduction in drop seizures as the dependent variable and treatment, pooled center, and baseline drop seizure rate as the independent variables. A step-down procedure used, starting with the high dose versus placebo.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	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 Percent Reduction of Total (Drop and Non-Drop) Seizures.

Groups [1]	Clobazam Medium Dose vs. Placebo
Method [2]	ANCOVA
P Value [3]	0.0044

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	ANCOVA with the percent reduction in drop seizures as the dependent variable and treatment, pooled center, and baseline drop seizure rate as the independent variables. A step-down procedure used, starting with the high dose versus placebo.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	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 3 for Percent Reduction of Total (Drop and Non-Drop) Seizures.

Groups [1]	Clobazam High Dose vs. Placebo
Method [2]	ANCOVA
P Value [3]	<0.0001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	ANCOVA with the percent reduction in drop seizures as the dependent variable and treatment, pooled center, and baseline drop seizure rate as the independent variables. A step-down procedure used, starting with the high dose versus placebo.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	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	19 weeks
Additional Description	No text entered.

Reporting Groups

	Description
Clobazam Low Dose	0.25 mg/kg/day; tablets; orally; for 15-18 weeks
Clobazam Medium Dose	0.5 mg/kg/day; tablets; orally; for 15-18 weeks
Clobazam High Dose	1.0 mg/kg/day; tablets; orally; for 15-18 weeks
Placebo	tablets; orally; daily for 15-18 weeks

Serious Adverse Events

	Clobazam Low Dose	**Clobazam Medium Dose**	**Clobazam High Dose**	**Placebo**
Total, serious adverse events				
# participants affected / at risk	**3/58 (5.17%)**	**6/62 (9.68%)**	**5/59 (8.47%)**	**2/59 (3.39%)**
Blood and lymphatic system disorders				
Thrombocytopenia † 2				
# participants affected / at risk	**0/58 (0.00%)**	**1/62 (1.61%)**	**0/59 (0.00%)**	**0/59 (0.00%)**
Cardiac disorders				
Cyanosis † 2				
# participants affected / at risk	**0/58 (0.00%)**	**1/62 (1.61%)**	**0/59 (0.00%)**	**0/59 (0.00%)**
Gastrointestinal disorders				
Vomiting † 2				
# participants affected / at risk	**0/58 (0.00%)**	**1/62 (1.61%)**	**0/59 (0.00%)**	**0/59 (0.00%)**
Constipation † 2				

# participants affected / at risk	0/58 (0.00%)	0/62 (0.00%)	1/59 (1.69%)	0/59 (0.00%)
General disorders				
Adverse drug reaction † 2				
# participants affected / at risk	1/58 (1.72%)	0/62 (0.00%)	0/59 (0.00%)	0/59 (0.00%)
Infections and infestations				
Lobar pneumonia † 2				
# participants affected / at risk	0/58 (0.00%)	0/62 (0.00%)	2/59 (3.39%)	1/59 (1.69%)
Metapneumovirus infection † 2				
# participants affected / at risk	1/58 (1.72%)	0/62 (0.00%)	0/59 (0.00%)	0/59 (0.00%)
Pneumonia † 2				
# participants affected / at risk	2/58 (3.45%)	2/62 (3.23%)	1/59 (1.69%)	0/59 (0.00%)
Rhinovirus infection † 2				
# participants affected / at risk	1/58 (1.72%)	0/62 (0.00%)	0/59 (0.00%)	0/59 (0.00%)
Influenza † 2				
# participants affected / at risk	0/58 (0.00%)	0/62 (0.00%)	1/59 (1.69%)	0/59 (0.00%)
Parainfluenzae virus infection † 2				
# participants affected / at risk	0/58 (0.00%)	0/62 (0.00%)	1/59 (1.69%)	0/59 (0.00%)
Bronchopneumonia † 2				
# participants affected / at risk	0/58 (0.00%)	0/62 (0.00%)	1/59 (1.69%)	0/59 (0.00%)
Injury, poisoning and procedural complications				
Jaw fracture † 1				
# participants affected / at risk	0/58 (0.00%)	0/62 (0.00%)	0/59 (0.00%)	1/59 (1.69%)
Drug administration error † 2				
# participants affected / at risk	0/58 (0.00%)	1/62 (1.61%)	0/59 (0.00%)	0/59 (0.00%)
Drug toxicity † 2				
# participants affected / at risk	0/58 (0.00%)	1/62 (1.61%)	0/59 (0.00%)	0/59 (0.00%)
Investigations				
Ultrasound abdomen abnormal † 2				
# participants affected / at risk	0/58 (0.00%)	0/62 (0.00%)	1/59 (1.69%)	0/59 (0.00%)
Nervous system disorders				
Sedation † 2				
# participants affected / at risk	1/58 (1.72%)	0/62 (0.00%)	0/59 (0.00%)	0/59 (0.00%)
Headache † 2				
# participants affected / at risk	0/58 (0.00%)	1/62 (1.61%)	0/59 (0.00%)	0/59 (0.00%)
Myoclonic epilepsy † 2				
# participants affected / at risk	0/58 (0.00%)	1/62 (1.61%)	0/59 (0.00%)	0/59 (0.00%)
Grand mal convulsion † 2				
# participants affected / at risk	0/58 (0.00%)	0/62 (0.00%)	1/59 (1.69%)	0/59 (0.00%)
Psychiatric disorders				
Depressed level of consciousness † 2				
# participants affected / at risk	0/58 (0.00%)	0/62 (0.00%)	1/59 (1.69%)	0/59 (0.00%)
Respiratory, thoracic and mediastinal disorders				
Respiratory failure † 2				
# participants affected / at risk	0/58 (0.00%)	0/62 (0.00%)	1/59 (1.69%)	0/59 (0.00%)

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 12.0
2 Term from vocabulary, MedDRA (12.0)

Other Adverse Events

Hide Other Adverse Events

Time Frame	19 weeks
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5

Reporting Groups

	Description
Clobazam Low Dose	0.25 mg/kg/day; tablets; orally; for 15-18 weeks
Clobazam Medium Dose	0.5 mg/kg/day; tablets; orally; for 15-18 weeks
Clobazam High Dose	1.0 mg/kg/day; tablets; orally; for 15-18 weeks
Placebo	tablets; orally; daily for 15-18 weeks

Other Adverse Events

	Clobazam Low Dose	Clobazam Medium Dose	Clobazam High Dose	Placebo
Total, other (not including serious) adverse events				
# participants affected / at risk	**42/58 (72.41%)**	**55/62 (88.71%)**	**45/59 (76.27%)**	**40/59 (67.80%)**
Gastrointestinal disorders				
Constipation † 1				
# participants affected / at risk	**1/58 (1.72%)**	**1/62 (1.61%)**	**6/59 (10.17%)**	**0/59 (0.00%)**
Diarrhoea † 1				
# participants affected / at risk	**4/58 (6.90%)**	**2/62 (3.23%)**	**3/59 (5.08%)**	**4/59 (6.78%)**
Dysphagia † 1				
# participants affected / at risk	**0/58 (0.00%)**	**0/62 (0.00%)**	**3/59 (5.08%)**	**0/59 (0.00%)**
Vomiting † 1				
# participants affected / at risk	**5/58 (8.62%)**	**3/62 (4.84%)**	**4/59 (6.78%)**	**3/59 (5.08%)**
General disorders				
Fatigue † 1				
# participants affected / at risk	**3/58 (5.17%)**	**3/62 (4.84%)**	**2/59 (3.39%)**	**1/59 (1.69%)**
Irritability † 1				
# participants affected / at risk	**2/58 (3.45%)**	**7/62 (11.29%)**	**3/59 (5.08%)**	**3/59 (5.08%)**
Pyrexia † 1				
# participants affected / at risk	**10/58 (17.24%)**	**6/62 (9.68%)**	**7/59 (11.86%)**	**2/59 (3.39%)**
Infections and infestations				
Bronchitis † 1				
# participants affected / at risk	**1/58 (1.72%)**	**0/62 (0.00%)**	**3/59 (5.08%)**	**0/59 (0.00%)**
† 1				

Nasopharyngitis				
# participants affected / at risk	5/58 (8.62%)	6/62 (9.68%)	4/59 (6.78%)	6/59 (10.17%)
Upper respiratory tract infection † 1				
# participants affected / at risk	6/58 (10.34%)	8/62 (12.90%)	8/59 (13.56%)	6/59 (10.17%)
Urinary tract infection † 1				
# participants affected / at risk	1/58 (1.72%)	3/62 (4.84%)	3/59 (5.08%)	0/59 (0.00%)
Injury, poisoning and procedural complications				
Contusion † 1				
# participants affected / at risk	2/58 (3.45%)	2/62 (3.23%)	2/59 (3.39%)	3/59 (5.08%)
Excoriation † 1				
# participants affected / at risk	0/58 (0.00%)	1/62 (1.61%)	2/59 (3.39%)	5/59 (8.47%)
Fall † 1				
# participants affected / at risk	0/58 (0.00%)	1/62 (1.61%)	0/59 (0.00%)	3/59 (5.08%)
Skin Laceration † 1				
# participants affected / at risk	1/58 (1.72%)	0/62 (0.00%)	2/59 (3.39%)	3/59 (5.08%)
Investigations				
Blood bicarbonate decreased † 1				
# participants affected / at risk	1/58 (1.72%)	0/62 (0.00%)	2/59 (3.39%)	3/59 (5.08%)
Metabolism and nutrition disorders				
Decreased appetite † 1				
# participants affected / at risk	2/58 (3.45%)	0/62 (0.00%)	4/59 (6.78%)	2/59 (3.39%)
Increased appetite † 1				
# participants affected / at risk	1/58 (1.72%)	2/62 (3.23%)	3/59 (5.08%)	0/59 (0.00%)
Nervous system disorders				
Ataxia † 1				
# participants affected / at risk	2/58 (3.45%)	1/62 (1.61%)	6/59 (10.17%)	2/59 (3.39%)
Drooling † 1				
# participants affected / at risk	0/58 (0.00%)	8/62 (12.90%)	8/59 (13.56%)	2/59 (3.39%)
Dysarthria † 1				
# participants affected / at risk	1/58 (1.72%)	1/62 (1.61%)	3/59 (5.08%)	0/59 (0.00%)
Lethargy † 1				
# participants affected / at risk	6/58 (10.34%)	3/62 (4.84%)	9/59 (15.25%)	3/59 (5.08%)
Psychomotor hyperactivity † 1				
# participants affected / at risk	2/58 (3.45%)	2/62 (3.23%)	3/59 (5.08%)	2/59 (3.39%)
Sedation † 1				
# participants affected / at risk	1/58 (1.72%)	2/62 (3.23%)	5/59 (8.47%)	2/59 (3.39%)
Somnolence † 1				
# participants affected / at risk	9/58 (15.52%)	15/62 (24.19%)	15/59 (25.42%)	7/59 (11.86%)
Tremor † 1				
# participants affected / at risk	1/58 (1.72%)	4/62 (6.45%)	1/59 (1.69%)	0/59 (0.00%)
Psychiatric disorders				
Aggression † 1				
# participants affected / at risk	2/58 (3.45%)	5/62 (8.06%)	8/59 (13.56%)	3/59 (5.08%)
Insomnia † 1				
# participants affected / at risk	1/58 (1.72%)	3/62 (4.84%)	4/59 (6.78%)	1/59 (1.69%)

Respiratory, thoracic and mediastinal disorders				
Cough † 1				
# participants affected / at risk	**2/58 (3.45%)**	**3/62 (4.84%)**	**4/59 (6.78%)**	**0/59 (0.00%)**
Nasal congestion † 1				
# participants affected / at risk	**3/58 (5.17%)**	**0/62 (0.00%)**	**1/59 (1.69%)**	**1/59 (1.69%)**
Skin and subcutaneous tissue disorders				
Rash † 1				
# participants affected / at risk	**1/58 (1.72%)**	**2/62 (3.23%)**	**3/59 (5.08%)**	**2/59 (3.39%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA (12.0)

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.

Restriction Description: The sponsor must have the opportunity to review and approve all proposed abstracts, manuscripts, or presentations regarding this study prior to submission for publication/presentation. Any information identified by the Sponsor as confidential must be deleted prior to submission.

Results Point of Contact:

Name/Title: Email contact via H. Lundbeck A/S
Organization: Lundbeck LLC
e-mail: LundbeckClinicalTrials@lundbeck.com

Publications of Results:

Ng YT, Conry JA, Drummond R, Stolle J, Weinberg MA; OV-1012 Study Investigators.. Randomized, phase III study results of clobazam in Lennox-Gastaut syndrome. Neurology. 2011 Oct 11;77(15):1473-81. doi: 10.1212/WNL.0b013e318232de76.

Responsible Party:	Lundbeck LLC
ClinicalTrials.gov Identifier:	NCT00518713 History of Changes
Other Study ID Numbers:	**13110A** OV1012 (Other Identifier: Former study ID)
Study First Received:	August 20, 2007
Results First Received:	November 7, 2011
Last Updated:	January 6, 2012
Health Authority:	Australia: Department of Health and Ageing Therapeutic Goods Administration Belarus: Ministry of Health India: Drugs Controller General of India Lithuania: State Medicine Control Agency - Ministry of Health United States: Food and Drug Administration

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