Multiple Period Study Design Example (With Results)

This study has been completed.

Sponsor: PRS Results Training

Information provided by (Responsible Party): PRS Results Training

Disclaimer: The following information is fictional and is only intended for the purpose of illustrating key concepts for results data entry in the Protocol Registration and Results System (PRS).

Full Text View

Purpose

The purpose of this study is to assess the efficacy of Vuxcluglyn for Symptom P in participants with Condition A.

Condition	Intervention	Phase
Condition A	Drug: Vuxcluglyn Drug: Placebo	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Primary Purpose: Treatment

Official Title: A Phase III Double-Blind Randomized Placebo-Controlled Trial Followed by an Open-Label Period to Assess Vuxcluglyn for Symptom P in Participants With Condition A

Further study details as provided by PRS Results Training

Primary Outcome Measure:

- Composite Intervention Outcome Scale (CIOS) at 5 Hours Following Administration of Vuxcluglyn or Placebo During the Double-Blind Period [Time Frame: 5 Hours] [Designated as safety issue: No]

  CIOS is a validated, composite measure of response, based on the participant's perception of improvement at assessment. It is composed of 5 items (individually scored from 0 to 10) with total possible values ranging from 0 (no improvement) to 50 (complete resolution), with a score ≥ 25 indicating clinically meaningful improvement.

Secondary Outcome Measures:

- Change From Baseline in Symptom Severity Rating (SSR) at 5 Hours After Administration of Vuxcluglyn or Placebo During the Double-Blind Period [Time Frame: Baseline and 5 Hours] [Designated as safety issue: No]

  SSR is a validated, patient-reported measure of symptom severity. SSR values range from 0 (no symptoms) and 5 (severe). Scores are also provided for SSR at 5 hours post-dose, in addition to the change from baseline. Change = (5 hour rating - Baseline rating)

- Composite Intervention Outcome Scale (CIOS) at 5 Hours After Administration of Dose 1 of Vuxcluglyn During the Open-Label Period [Time Frame: 5 Hours] [Designated as safety issue: No]

  CIOS is a validated, composite measure of response, based on the participant's perception of improvement at assessment. It is composed of 5 items (individually scored from 0 to 10) with total possible values ranging from 0 (no improvement) to 50 (complete resolution), with a score ≥ 25 indicating clinically meaningful improvement.

- Composite Intervention Outcome Scale (CIOS) at 5 Hours After Administration of Dose 2 of Vuxcluglyn During the Open-Label Period [Time Frame: 5 Hours] [Designated as safety issue: No]

  CIOS is a validated, composite measure of response, based on the participant's perception of improvement at assessment. It is composed of 5 items (individually scored from 0 to 10) with total possible values ranging from 0 (no improvement) to 50 (complete resolution), with a score ≥ 25 indicating clinically meaningful improvement.

- Composite Intervention Outcome Scale (CIOS) at 5 Hours After Administration of Dose 3 of Vuxcluglyn During the Open-Label Period [Time Frame: 5 Hours] [Designated as safety issue: No]

  CIOS is a validated, composite measure of response, based on the participant's perception of improvement at assessment. It is composed of 5 items (individually scored from 0 to 10) with total possible values ranging from 0 (no improvement) to 50 (complete resolution), with a score ≥ 25 indicating clinically meaningful improvement.

- Composite Intervention Outcome Scale (CIOS) at 5 Hours After Administration of Dose 4 of Vuxcluglyn During the Open-Label Period [Time Frame: 5 Hours] [Designated as safety issue: No]

  CIOS is a validated, composite measure of response, based on the participant's perception of improvement at assessment. It is composed of 5 items (individually scored from 0 to 10) with total possible values ranging from 0 (no improvement) to 50 (complete resolution), with a score ≥ 25 indicating clinically meaningful improvement.

- Composite Intervention Outcome Scale (CIOS) at 5 Hours After Administration of Dose 5 of Vuxcluglyn During the Open-Label Period [Time Frame: 5 Hours] [Designated as safety issue: No]

  CIOS is a validated, composite measure of response, based on the participant's perception of improvement at assessment. It is composed of 5 items (individually scored from 0 to 10) with total possible values ranging from 0 (no improvement) to 50 (complete resolution), with a score ≥ 25 indicating clinically meaningful improvement.

Enrollment:	250
Study Start Date:	December 2008
Study Completion Date:	January 2010
Primary Completion Date:	June 2009

Arms	Assigned Interventions
Experimental: Double-Blind Vuxcluglyn Enrolled participants presenting Symptom P were randomized to a single dose of Vuxcluglyn, 100 mg capsule, by mouth (PO). These participants were observed after administration of the intervention. Symptoms were assessed every 30 minutes for 6 hours and then at 12 hours.	Drug: Vuxcluglyn 100 mg capsule by mouth (PO)
Placebo Comparator: Double-Blind Placebo Enrolled participants presenting Symptom P were randomized to a single dose of placebo by mouth (PO). These participants were observed after administration of the intervention. Symptoms were assessed every 30 minutes for 6 hours and then at 12 hours.	Drug: Placebo Placebo capsule by mouth (PO)
Experimental: Open-Label Vuxcluglyn All enrolled participants were eligible to receive a single dose of Vuxcluglyn, 100 mg capsule, PO, for each episode of Symptom P experienced, whether or not they had participated in the previous Double-Blind Period. These participants were observed after each administration of Vuxcluglyn. Symptoms will be assessed every 30 minutes for 6 hours and then at 12 hours.	Drug: Vuxcluglyn 100 mg capsule by mouth (PO)

Detailed Description

This study will enroll participants with Condition A from 3 research sites: The Johns Hopkins Hospital (Baltimore, MD, USA), Mount Sinai Hospital (Toronto, Ontario, Canada), and George Eliot Hospital (Nuneaton, England, UK).

After being informed about the study and its potential risks, patients with Condition A will be screened for eligibility. The study will be conducted in two successive periods. All enrolled participants who present at a study site with Symptom P will be randomized in the Double-Blind Period. Following completion of that period, all participants enrolled in the study will be eligible to participate in the Open-Label Period, whether or not they were randomized to an intervention in the Double-Blind Period.

During the initial Double-Blind Period, enrolled participants presenting with Symptom P will be randomized in a 1:1 ratio to a single dose of Vuxcluglyn, 100 mg capsule, by mouth (PO), or matching placebo. These participants will be observed after administration of the intervention. Symptoms will be assessed every 30 minutes for 6 hours and then at 12 hours.

During the subsequent, Open Label Period, all enrolled patients will be eligible to receive a single dose of Vuxcluglyn, 100 mg capsule, PO, for each episode of Symptom P experienced, whether or not they had participated in the previous Double-Blind Period. These participants will be observed after each administration of the Vuxcluglyn. Symptoms will be assessed every 30 minutes for 6 hours and then at 12 hours.

Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Inclusion Criteria

- Diagnosis of Condition A
- A stable medical regimen for at least 4 weeks prior to enrollment
- Required to have a sufficient level of education to understand study procedures and be able to communicate with site personnel

Exclusion Criteria

- Uncontrolled medical disease (e.g., cardiovascular, renal)
- Body mass index < 16.5 kg/m^2
- Pregnancy and/or lactation
- History of hypersensitivity to Vuxcluglyn or any similar chemical structures

Contacts and Locations

Locations

United States, Maryland

Johns Hopkins Hospital
Baltimore, Maryland, United States

Canada, Ontario

Mount Sinai Hospital
Toronto, Ontario, Canada

United Kingdom

George Eliot Hospital
Nuneaton, England, United Kingdom

More Information

Responsible Party: PRS Results Training
Study ID Numbers: TTTMultiplePeriodR
Health Authority: United States: Food and Drug Administration

Study Results

Participant Flow

Recruitment Details (Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations.)

Of the 350 participants screened at 3 hospitals, 250 participants were enrolled between December 2008 and February 2009.

Reporting Groups

	Description
Double-Blind Vuxcluglyn, Then Open-Label Vuxcluglyn	Double-Blind Period: Enrolled participants presenting Symptom P were randomized to a single dose of Vuxcluglyn, 100 mg capsule, by mouth (PO). These participants were observed after administration of Vuxcluglyn. Symptoms were assessed every 30 minutes for 6 hours and then at 12 hours. Open-Label Period: Participants were eligible to receive a single dose of Vuxcluglyn, 100 mg capsule, PO, for each episode of Symptom P experienced. These participants were observed after each administration of Vuxcluglyn and symptoms were assessed every 30 minutes for 6 hours and then at 12 hours.
Double-Blind Placebo, Then Open-Label Vuxcluglyn	Double-Blind Period: Enrolled participants presenting Symptom P were randomized to a single dose of placebo capsule, by mouth (PO). These participants were observed after administration of Placebo. Symptoms were assessed every 30 minutes for 6 hours and then at 12 hours. Open-Label Period: Participants were eligible to receive a single dose of Vuxcluglyn, 100 mg capsule, PO, for each episode of Symptom P experienced. These participants were observed after each administration of Vuxcluglyn and symptoms were assessed every 30 minutes for 6 hours and then at 12 hours.
Open-Label Vuxcluglyn	Participants who did not experience Symptom P at time of enrollment were assigned directly to Open-Label. If a participant experienced Symptom P, they were eligible to receive a single dose of Vuxcluglyn, 100 mg capsule, PO, for each episode of Symptom P experienced. These participants were observed after each administration of Vuxcluglyn. Symptoms were assessed every 30 minutes for 6 hours and then at 12 hours.

Double-Blind Period

	Number of Participants		
	Double-Blind Vuxcluglyn, Then Open-Label Vuxcluglyn	**Double-Blind Placebo, Then Open-Label Vuxcluglyn**	**Open-Label Vuxcluglyn**
STARTED	**50**	**50**	**0**
COMPLETED	**45**	**50**	**0**
Not Completed	**5**	**0**	**0**
Lost to Follow-up	5	0	0

Open-Label Period

	Number of Participants		
	Double-Blind Vuxcluglyn, Then Open-Label Vuxcluglyn	Double-Blind Placebo, Then Open-Label Vuxcluglyn	Open-Label Vuxcluglyn
STARTED	**45**	**50**	**150**
Had Symptom P & Received Vuxcluglyn	36	44	40
COMPLETED	**31**	**40**	**37**
Not Completed	**14**	**10**	**113**
Did not experience Symptom P	9	6	110
Adverse Event	3	2	3
Lost to Follow-up	1	1	0
Physician Decision	1	0	0
Unknown	0	1	0

Baseline Characteristics

Analysis 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.)

Baseline Characteristics are reported for participants who experienced Symptom P and received Vuxcluglyn.

Reporting Groups

	Description
Double-Blind Vuxcluglyn	Participants presenting with Symptom P at the time of enrollment and were randomized to a single dose of Vuxcluglyn, 100 mg capsule, by mouth (PO). These participants were observed after administration of Vuxcluglyn. Symptoms were assessed every 30 minutes for 6 hours and then at 12 hours.
Double-Blind Placebo	Participants presenting with Symptom P at the time of enrollment and were randomized to a single dose of Vuxcluglyn-matched Placebo, by mouth (PO). These participants were observed after administration of Vuxcluglyn. Symptoms were assessed every 30 minutes for 6 hours and then at 12 hours.
Open-Label Vuxcluglyn	Participants who were not experiencing Symptom P at the time of randomization, but did experience Symptom P during the Open-Label Period, and received at least one dose of Vuxcluglyn, 100 mg capsule, PO. Participants were eligible to receive a single dose of Vuxcluglyn for each episode of Symptom P experienced, whether or not they had participated in the previous Double-Blind Period. These participants were observed after each administration of Vuxcluglyn. Symptoms were assessed every 30 minutes for 6 hours and then at 12 hours.

Baseline Measures

	Double-Blind Vuxcluglyn	Double-Blind Placebo	Open-Label Vuxcluglyn	Total
Number of Participants	50	50	40	140
Age Continuous [units: years] Mean ± Standard Deviation	31.7 ± 13.4	32.3 ± 16.4	30.5 ± 14.1	31.5 ± 18.2
Gender, Male/Female [units: participants]				
Female	35	27	22	84
Male	15	23	18	56
Race/Ethnicity, Customized [units: participants]				
Black	21	22	18	61
White	26	24	20	70
Hispanic	3	4	2	9
Region of Enrollment [units: participants]				
United States	25	25	16	66
Canada	15	10	12	37
United Kingdom	10	15	12	37
Weight [units: pounds (lbs)] Median (Full Range)	161 (128 to 279)	142 (117 to 311)	156 (99 to 325)	156 (99 to 325)
Symptom Severity Rating (SSR) Score [A] [units: units on a scale] Mean ± Standard Deviation	3.12 ± 0.61	3.05 ± 0.45	NA ± NA [B]	3.09 ± 0.51

[A] SSR score is a validated, patient-reported measure of symptom severity. SSR values range from 0 (no symptoms) and 5 (severe).

[B] The SSR was only administered at baseline in the double-blind period.

Outcome Measures

1. Primary Outcome Measure

Measure Title	Composite Intervention Outcome Scale (CIOS) at 5 Hours Following Administration of Vuxcluglyn or Placebo During the Double-Blind Period
Measure Description	CIOS is a validated, composite measure of response, based on the participant's perception of improvement at assessment. It is composed of 5 items (individually scored from 0 to 10) with total possible values ranging from 0 (no improvement) to 50 (complete resolution), with a score ≥ 25 indicating clinically meaningful improvement.
Time Frame	5 Hours
Safety Issue	No

Analysis 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
Double-Blind Vuxcluglyn	A single dose of Vuxcluglyn, 100 mg capsule, by mouth (PO) in the Double-Blind Period.
Double-Blind Placebo	A single dose of Placebo capsule (matching Vuxcluglyn), by mouth (PO) in the Double-Blind Period.

Measured Values

	Double-Blind Vuxcluglyn	Double-Blind Placebo
Number of Participants Analyzed	50	50
Composite Intervention Outcome Scale (CIOS) at 5 Hours Following Administration of Vuxcluglyn or Placebo During the Double-Blind Period [units: units on a scale] Mean ± Standard Deviation	33.9 ± 10.2	12.7 ± 5.6

Statistical Analysis 1 for Composite Intervention Outcome Scale (CIOS) at 5 Hours Following Administration of Vuxcluglyn or Placebo During the Double-Blind Period

Groups	Double-Blind Vuxcluglyn, Double-Blind Placebo
Method	t-test, 2-sided
P-value	0.004

2. Secondary Outcome Measure

Measure Title	Change From Baseline in Symptom Severity Rating (SSR) at 5 Hours After Administration of Vuxcluglyn or Placebo During the Double-Blind Period
Measure Description	SSR is a validated, patient-reported measure of symptom severity. SSR values range from 0 (no symptoms) and 5 (severe). Scores are also provided for SSR at 5 hours post-dose, in addition to the change from baseline. Change = (5 hour rating - Baseline rating)
Time Frame	Baseline and 5 Hours
Safety Issue	No

Analysis 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
Double-Blind Vuxcluglyn	A single dose of Vuxcluglyn, 100 mg capsule, by mouth (PO) in the Double-Blind Period.
Double-Blind Placebo	A single dose of Placebo capsule (matching Vuxcluglyn), by mouth (PO) in the Double-Blind Period.

Measured Values

	Double-Blind Vuxcluglyn	Double-Blind Placebo
Number of Participants Analyzed	50	50
Change From Baseline in Symptom Severity Rating (SSR) at 5 Hours After Administration of Vuxcluglyn or Placebo During the Double-Blind Period [units: units on a scale] Mean ± Standard Deviation		
SSR Score at 5 Hours Post-Dose	1.17 ± 0.22	1.97 ± 0.36
Change from Baseline in SSR at 5 Hours	-1.95 ± 0.68	-1.08 ± 0.71

Statistical Analysis 1 for Change From Baseline in Symptom Severity Rating (SSR) at 5 Hours After Administration of Vuxcluglyn or Placebo During the Double-Blind Period

Groups [A]	Double-Blind Vuxcluglyn, Double-Blind Placebo
Method	t-test, 2-sided
P-value	0.044

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

Null Hypothesis = There is no difference between DB Vuxcluglyn and DB Placebo in the "Change from Baseline in SSR at 5 Hours."

3. Secondary Outcome Measure

Measure Title	Composite Intervention Outcome Scale (CIOS) at 5 Hours After Administration of Dose 1 of Vuxcluglyn During the Open-Label Period
Measure Description	CIOS is a validated, composite measure of response, based on the participant's perception of improvement at assessment. It is composed of 5 items (individually scored from 0 to 10) with total possible values ranging from 0 (no improvement) to 50 (complete resolution), with a score ≥ 25 indicating clinically meaningful improvement.
Time Frame	5 Hours
Safety Issue	No

Analysis 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.)

All participants who received dose 1 of Vuxcluglyn in the Open-Label period.

Reporting Groups

	Description
Vuxcluglyn	All participants who experienced Symptom P and who first received a dose of Vuxcluglyn, 100 mg capsule, by mouth (PO) in the Open-Label Period. These participants were either assigned to placebo in the double-blind period or were assigned directly to the Open-Label period.

Measured Values

	Vuxcluglyn
Number of Participants Analyzed	84
Composite Intervention Outcome Scale (CIOS) at 5 Hours After Administration of Dose 1 of Vuxcluglyn During the Open-Label Period [units: units on a scale] Mean ± Standard Deviation	32.21 ± 5.17

4. Secondary Outcome Measure

Measure Title	Composite Intervention Outcome Scale (CIOS) at 5 Hours After Administration of Dose 2 of Vuxcluglyn During the Open-Label Period
Measure Description	CIOS is a validated, composite measure of response, based on the participant's perception of improvement at assessment. It is composed of 5 items (individually scored from 0 to 10) with total possible values ranging from 0 (no improvement) to 50 (complete resolution), with a score ≥ 25 indicating clinically meaningful improvement.
Time Frame	5 Hours
Safety Issue	No

Analysis 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.)

All participants who received at least 2 doses of Vuxcluglyn over the course of the entire study (i.e., Double Blind + Open Label periods combined).

Reporting Groups

	Description
Vuxcluglyn	All participants who experienced Symptom P and who received a second dose of Vuxcluglyn, 100 mg capsule, by mouth (PO) in the Open-Label Period. Participants could have received their first dose in the Open-Label or Double-Blind Period.

Measured Values

	Vuxcluglyn
Number of Participants Analyzed	99
Composite Intervention Outcome Scale (CIOS) at 5 Hours After Administration of Dose 2 of Vuxcluglyn During the Open-Label Period [units: units on a scale] Mean ± Standard Deviation	42.03 ± 8.25

5. Secondary Outcome Measure

Measure Title	Composite Intervention Outcome Scale (CIOS) at 5 Hours After Administration of Dose 3 of Vuxcluglyn During the Open-Label Period
Measure Description	CIOS is a validated, composite measure of response, based on the participant's perception of improvement at assessment. It is composed of 5 items (individually scored from 0 to 10) with total possible values ranging from 0 (no improvement) to 50 (complete resolution), with a score ≥ 25 indicating clinically meaningful improvement.
Time Frame	5 Hours
Safety Issue	No

Analysis 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.)

All participants who received at least 3 doses of Vuxcluglyn over the course of the entire study (i.e., Double Blind + Open Label periods combined).

Reporting Groups

	Description
Vuxcluglyn	All participants who experienced Symptom P and who received a third dose of Vuxcluglyn, 100 mg capsule, by mouth (PO) in the Open-Label Period.

Measured Values

	Vuxcluglyn
Number of Participants Analyzed	46
Composite Intervention Outcome Scale (CIOS) at 5 Hours After Administration of Dose 3 of Vuxcluglyn During the Open-Label Period [units: units on a scale] Mean ± Standard Deviation	35.95 ± 4.68

6. Secondary Outcome Measure

Measure Title	Composite Intervention Outcome Scale (CIOS) at 5 Hours After Administration of Dose 4 of Vuxcluglyn During the Open-Label Period
Measure Description	CIOS is a validated, composite measure of response, based on the participant's perception of improvement at assessment. It is composed of 5 items (individually scored from 0 to 10) with total possible values ranging from 0 (no improvement) to 50 (complete resolution), with a score ≥ 25 indicating clinically meaningful improvement.
Time Frame	5 Hours
Safety Issue	No

Analysis 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.)

All participants who received at least 4 doses of Vuxcluglyn over the course of the entire study (i.e., Double Blind + Open Label periods combined).

Reporting Groups

	Description
Vuxcluglyn	All participants who experienced Symptom P and who received a fourth dose of Vuxcluglyn, 100 mg capsule, by mouth (PO) in the Open-Label Period.

Measured Values

	Vuxcluglyn
Number of Participants Analyzed	26
Composite Intervention Outcome Scale (CIOS) at 5 Hours After Administration of Dose 4 of Vuxcluglyn During the Open-Label Period [units: units on a scale] Mean ± Standard Deviation	22.44 ± 1.51

7. Secondary Outcome Measure

Measure Title	Composite Intervention Outcome Scale (CIOS) at 5 Hours After Administration of Dose 5 of Vuxcluglyn During the Open-Label Period
Measure Description	CIOS is a validated, composite measure of response, based on the participant's perception of improvement at assessment. It is composed of 5 items (individually scored from 0 to 10) with total possible values ranging from 0 (no improvement) to 50 (complete resolution), with a score ≥ 25 indicating clinically meaningful improvement.
Time Frame	5 Hours
Safety Issue	No

Analysis 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.)

All participants who received at least 5 doses of Vuxcluglyn over the course of the entire study (i.e., Double Blind + Open Label periods combined).

Reporting Groups

	Description
Vuxcluglyn	All participants who experienced Symptom P and who received a fifth dose of Vuxcluglyn, 100 mg capsule, by mouth (PO) in the Open-Label Period.

Measured Values

	Vuxcluglyn
Number of Participants Analyzed	15
Composite Intervention Outcome Scale (CIOS) at 5 Hours After Administration of Dose 5 of Vuxcluglyn During the Open-Label Period [units: units on a scale] Mean ± Standard Deviation	18.15 ± 8.98

Adverse Events

Time Frame	[No text entered.]
Additional Description	Safety Population was composed of participants who received at least one dose of Vuxcluglyn or Placebo

Reporting Groups

	Description
Double-Blind Vuxcluglyn	Enrolled participants presenting Symptom P were randomized to a single dose of Vuxcluglyn, 100 mg capsule, by mouth (PO) in the Double-Blind Period.
Double-Blind Placebo	Enrolled participants presenting Symptom P were randomized to a single dose of placebo by mouth (PO) in the Double-Blind Period.
Open-Label Vuxcluglyn	All enrolled participants who received at least one dose of Vuxcluglyn, 100 mg capsule, PO, during the Open-Label Period. Participants were eligible to receive one dose of Vuxcluglyn for each episode of Symptom P experienced, whether or not they had participated in the previous Double-Blind Period.

Serious Adverse Events

	# Participants Affected/At Risk		
	Double-Blind Vuxcluglyn	**Double-Blind Placebo**	**Open-Label Vuxcluglyn**
Total, serious adverse events	**3/50 (6%)**	**1/50 (2%)**	**2/120 (1.67%)**
Cardiac disorders			
Myocardial Infarction † 1	3/50 (6%)	0/50 (0%)	2/120 (1.67%)
General disorders			
Death † 1	0/50 (0%)	0/50 (0%)	1/120 (0.83%)
Nervous system disorders			
Hemorrhagic stroke † 1	1/50 (2%)	1/50 (2%)	0/120 (0%)

† Indicates events were collected by systematic assessment.
1 Term from vocabulary, MedDRA (10.0)

Other Adverse Events

Frequency Threshold

Threshold above which other adverse events are reported: 0%

	# Participants Affected/At Risk		
	Double-Blind Vuxcluglyn	Double-Blind Placebo	Open-Label Vuxcluglyn
Total, other (not including serious) adverse events	**16/50 (32%)**	**8/50 (16%)**	**42/120 (35%)**
Cardiac disorders			
Chest pain †1	4/50 (8%)	3/50 (6%)	12/120 (10%)
Palpitations †1	1/50 (2%)	0/50 (0%)	13/120 (10.83%)
Ventricular tachycardia †1	3/50 (6%)	2/50 (4%)	1/120 (0.83%)
Metabolism and nutrition disorders			
Hyperglycemia †1	2/50 (4%)	0/50 (0%)	15/120 (12.5%)
Nervous system disorders			
Dizziness †1	11/50 (22%)	5/50 (10%)	24/120 (20%)
Headache †1	11/50 (22%)	8/50 (16%)	36/120 (30%)
Respiratory, thoracic and mediastinal disorders			
Dyspnea †1	5/50 (10%)	2/50 (4%)	9/120 (7.5%)
Vascular disorders			
Hypertension †1	7/50 (14%)	1/50 (2%)	23/120 (19.17%)
Ischemia †1	4/50 (8%)	2/50 (4%)	37/120 (30.83%)

† Indicates events were collected by systematic assessment.
1 Term from vocabulary, MedDRA (10.0)

More Information

Certain Agreements

Principal Investigators are NOT employed by the organization sponsoring the study.

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 from the time submitted to the sponsor for review. The sponsor cannot require changes to the communication and cannot extend the embargo.

Limitations and Caveats (Limitations of the study, such as early termination leading to small numbers of subjects analyzed and technical problems with measurement leading to unreliable or uninterpretable data.)

[No text entered.]

Results Point of Contact

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