Multiple Period Study Design Example (With Results)

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).

ClinicalTrials.gov Identifier: NCT00055607

Recruitment Status: Completed
First Posted: July 23, 2017
Results First Posted: January 22, 2019
Last Update Posted: January 22, 2019

Sponsor:

PRS Results Training

Information provided by (Responsible Party):

PRS Results Training

Study Description

Brief Summary:

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

Condition or disease	Intervention/treatment	Phase
Condition A	Drug: Vuxcluglyn Drug: Placebo	Phase 3

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.

Study Design

Study Type:	Interventional
Actual Enrollment:	250 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	Double (Participant, Investigator)
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
Actual Study Start Date:	July 23, 2017
Actual Primary Completion Date:	January 25, 2018
Actual Study Completion Date:	August 20, 2018

Arms and Interventions

Arm	Intervention/treatment
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)

Outcome Measures

Primary Outcome Measure:

1. Composite Intervention Outcome Scale (CIOS) at 5 Hours Following Administration of Vuxcluglyn or Placebo During the Double-Blind Period [Time Frame: 5 Hours]

   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:

1. 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]

   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)

2. Composite Intervention Outcome Scale (CIOS) at 5 Hours After Administration of Dose 1 of Vuxcluglyn During the Open-Label Period [Time Frame: 5 Hours]

   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

3. Composite Intervention Outcome Scale (CIOS) at 5 Hours After Administration of Dose 2 of Vuxcluglyn During the Open-Label Period [Time Frame: 5 Hours]

   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.

4. Composite Intervention Outcome Scale (CIOS) at 5 Hours After Administration of Dose 3 of Vuxcluglyn During the Open-Label Period [Time Frame: 5 Hours]

   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.

5. Composite Intervention Outcome Scale (CIOS) at 5 Hours After Administration of Dose 4 of Vuxcluglyn During the Open-Label Period [Time Frame: 5 Hours]

   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.

6. Composite Intervention Outcome Scale (CIOS) at 5 Hours After Administration of Dose 5 of Vuxcluglyn During the Open-Label Period [Time Frame: 5 Hours]

   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.

Eligibility Criteria

Ages Eligible for Study: 18 Years and older (Adult, Older Adult)
Sexes Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Diagnosis of Condition A
- A stable medical regimen for at least 4 weeks prior to enrollment
- Hyperlipidemia
- 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, 21287

Canada, ON

Mount Sinai Hospital

Toronto, ON, Canada

United Kingdom

George Eliot Hospital

Nuneaton, England, United Kingdom

Study Documents (Full-Text)

Documents provided by PRS Results Training

Study Protocol and Statistical Analysis Plan [PDF] May 15, 2017

More Information

Responsible Party:	PRS Results Training
ClinicalTrials.gov Identifier:	NCT00055607
Other Study ID Numbers:	TTTMultiplePeriodR
First Posted:	July 23, 2017
Results First Posted:	January 22, 2019
Last Update Posted:	January 22, 2019
Last Verified:	December 2018

Human Subjects Protection Review Board Status:	Approved
Studies a U.S. FDA-regulated Drug Product:	Yes
Studies a U.S. FDA-regulated Device Product:	No

Study Results

Study Type	Interventional
Study Design	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Double (Participant, Investigator); Primary Purpose: Treatment
Condition	Condition A

Interventions	Drug: Vuxcluglyn Drug: Placebo
Enrollment	250

Participant Flow

Recruitment Details	Of the 350 participants screened at 3 hospitals, 250 participants were enrolled between July 23, 2017 and September 2017.
Pre-assignment Details	

Arm/Group Title	Double-Blind Vuxcluglyn, Then Open-Label Vuxcluglyn	Double-Blind Placebo, Then Open-Label Vuxcluglyn	Open-Label Vuxcluglyn
Arm/Group Description	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	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	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

	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.	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.	minutes for 6 hours and then at 12 hours.
Period Title: **Double-Blind Period**			
Started	50	50	0
Completed	45	50	0
Not Completed	5	0	0
Reason Not Completed			
Lost to Follow-up	5	0	0
Period Title: **Open-Label Period**			
Started	45	50	150
Had Symptom P & Received Vuxcluglyn	36	44	40
Completed	31	40	37
Not Completed	14	10	113
Reason Not Completed			
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

Arm/Group Title	Double-Blind Vuxcluglyn	Double-Blind Placebo	Open-Label Vuxcluglyn	Total
Arm/Group Description	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.	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.	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.	Total of all reporting groups

Overall Number of Baseline Participants		50	50	40	140
Baseline Analysis Population Description		Baseline Characteristics are reported for participants who experienced Symptom P and received Vuxcluglyn.			
Age, Continuous Mean (Standard Deviation) Unit of Measure: years					
	Number Analyzed	50 participants	50 participants	40 participants	140 participants
		31.7 (13.4)	32.3 (16.4)	30.5 (14.1)	31.6 (14.8)
Sex: Female, Male Measure Type: Count of Participants Unit of measure: participants					
	Number Analyzed	50 participants	50 participants	40 participants	140 participants
	Female	35 70%	27 54%	22 55%	84 60%
	Male	15 30%	23 46%	18 45%	56 40%

Ethnicity (NIH/OMB) Measure Type: Count of Participants Unit of measure: participants					
	Number Analyzed	50 participants	50 participants	40 participants	140 participants
	Hispanic or Latino	3 6%	4 8%	2 5%	9 6.43%
	Not Hispanic or Latino	47 94%	46 92%	38 95%	131 93.57%
	Unknown or Not Reported	0 0%	0 0%	0 0%	0 0%
Race (NIH/OMB) Measure Type: Count of Participants Unit of measure: participants					
	Number Analyzed	50 participants	50 participants	40 participants	140 participants
	American Indian or Alaska Native	0 0%	0 0%	0 0%	0 0%

	Asian	0	0%	0	0%	0	0%	0	0%
	Native Hawaiian or Other Pacific Islander	0	0%	0	0%	0	0%	0	0%
	Black or African American	21	42%	22	44%	18	45%	61	43.57%
	White	29	58%	28	56%	22	55%	79	56.43%
	More than one race	0	0%	0	0%	0	0%	0	0%
	Unknown or Not Reported	0	0%	0	0%	0	0%	0	0%
Region of Enrollment Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	50 participants		50 participants		40 participants		140 participants	
United States		25	50%	25	50%	16	40%	66	47.14%
Canada		15	30%	10	20%	12	30%	37	26.43%
United Kingdom		10	20%	15	30%	12	30%	37	26.43%

Weight Median (Full Range) Unit of measure: pounds (lbs)					
	Number Analyzed	50 participants	50 participants	40 participants	140 participants
		161 (128 to 279)	142 (117 to 311)	156 (99 to 325)	158 (99 to 325)
Symptom Severity Rating (SSR) Score [1] Mean (Standard Deviation) Unit of measure: units on a scale					
	Number Analyzed	50 participants	50 participants	0 participants	100 participants
		3.12 (0.61)	3.05 (0.45)	---	3.09 (0.54)
		[1] Measure Description: SSR score is a validated, patient-reported measure of symptom severity. SSR values range from 0 (no symptoms) and 5 (severe). [2] Measure Analysis Population Description: The SSR was only administered at baseline in the double-blind period.			

Outcome Measures

1. Primary Outcome

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

Outcome Measure Data

Analysis Population Description
[Not Specified]

Arm/Group Title	Double-Blind Vuxcluglyn	Double-Blind Placebo
Arm/Group Description:	A single dose of Vuxcluglyn, 100 mg capsule, by mouth (PO) in the Double-Blind Period.	A single dose of Placebo capsule (matching Vuxcluglyn), by mouth (PO) in the Double-Blind Period.
Overall Number of Participants Analyzed	50	50
Mean (Standard Deviation) Unit of Measure: units on a scale	33.9 (10.2)	12.7 (5.6)

Statistical Analysis 1

Statistical Analysis Overview	Comparison Group Selection	Double-Blind Vuxcluglyn, Double-Blind Placebo
	Comments	[Not specified]
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.004
	Comments	[Not specified]
	Method	t-test, 2 sided
	Comments	[Not specified]

2. Secondary Outcome

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

Outcome Measure Data

Analysis Population Description
[Not Specified]

Arm/Group Title	Double-Blind Vuxcluglyn	Double-Blind Placebo
Arm/Group Description:	A single dose of Vuxcluglyn, 100 mg capsule, by mouth (PO) in the Double-Blind Period.	A single dose of Placebo capsule (matching Vuxcluglyn), by mouth (PO) in the Double-Blind Period.
Overall Number of Participants Analyzed	50	50
Mean (Standard Deviation) Unit of Measure: units on a scale		
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

Statistical Analysis Overview	Comparison Group Selection	Double-Blind Vuxcluglyn, Double-Blind Placebo
	Comments	Null Hypothesis = There is no difference between DB Vuxcluglyn and DB Placebo in the "Change from Baseline in SSR at 5 Hours".
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.044
	Comments	[Not specified]
	Method	t-test, 2 sided
	Comments	[Not specified]

3. Secondary Outcome

Title	Composite Intervention Outcome Scale (CIOS) at 5 Hours After Administration of Dose 1 of Vuxcluglyn During the Open-Label Period
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

Outcome Measure Data

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

Arm/Group Title	Vuxcluglyn
Arm/Group Description:	All participants who experienced Symptom P and who received a first 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.
Overall Number of Participants Analyzed	84
Mean (Standard Deviation) Unit of Measure: units on a scale	32.21 (5.17)

4. Secondary Outcome

Title	Composite Intervention Outcome Scale (CIOS) at 5 Hours After Administration of Dose 2 of Vuxcluglyn During the Open-Label Period
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

Outcome Measure Data

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

Arm/Group Title	Vuxcluglyn
Arm/Group Description:	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.
Overall Number of Participants Analyzed	99
Mean (Standard Deviation) Unit of Measure: units on a scale	42.03 (8.25)

5. Secondary Outcome

Title	Composite Intervention Outcome Scale (CIOS) at 5 Hours After Administration of Dose 3 of Vuxcluglyn During the Open-Label Period
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

Outcome Measure Data

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

Arm/Group Title	Vuxcluglyn
Arm/Group Description:	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.
Overall Number of Participants Analyzed	46
Mean (Standard Deviation) Unit of Measure: units on a scale	35.95 (4.68)

6. Secondary Outcome

Title	Composite Intervention Outcome Scale (CIOS) at 5 Hours After Administration of Dose 4 of Vuxcluglyn During the Open-Label Period
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

Outcome Measure Data

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

Arm/Group Title	Vuxcluglyn
Arm/Group Description:	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.
Overall Number of Participants Analyzed	26
Mean (Standard Deviation) Unit of Measure: units on a scale	22.44 (1.51)

7. Secondary Outcome

Title	Composite Intervention Outcome Scale (CIOS) at 5 Hours After Administration of Dose 5 of Vuxcluglyn During the Open-Label Period
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

Outcome Measure Data

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

Arm/Group Title	Vuxcluglyn
Arm/Group Description:	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.
Overall Number of Participants Analyzed	15
Mean (Standard Deviation) Unit of Measure: units on a scale	18.15 (8.98)

Adverse Events

Time Frame	Up to 1 week following the final dose (up to 11 months post-enrollment)
Adverse Event Reporting Description	Safety Population was composed of participants who received at least one dose of Vuxcluglyn or Placebo
Source Vocabulary Name for Table Default	MedDRA (10.0)
Collection Approach for Table Default	Systematic Assessment

Arm/Group Title	Double-Blind Vuxcluglyn	Double-Blind Placebo	Open-Label Vuxcluglyn
Arm/Group Description	Enrolled participants presenting Symptom P were randomized to a single dose of Vuxcluglyn, 100 mg capsule, by mouth (PO) in the Double-Blind Period.	Enrolled participants presenting Symptom P were randomized to a single dose of placebo by mouth (PO) in the Double-Blind Period.	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.

All-Cause Mortality

	Double-Blind Vuxcluglyn	Double-Blind Placebo	Open-Label Vuxcluglyn
	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)
Total	0/50 (0%)	0/50 (0%)	1/120 (0.83%)

Serious Adverse Events

	Double-Blind Vuxcluglyn	Double-Blind Placebo	Open-Label Vuxcluglyn
	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)
Total	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%)
Nervous system disorders			
Hemorrhagic stroke †1	1/50 (2%)	1/50 (2%)	0/120 (0%)

1 Term from vocabulary, MedDRA (10.0)

† Indicates events were collected by systematic assessment

Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events	0%

	Double-Blind Vuxcluglyn	Double-Blind Placebo	Open-Label Vuxcluglyn
	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)
Total	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%)

1 Term from vocabulary, MedDRA (10.0)

† Indicates events were collected by systematic assessment

Limitations and Caveats

[Not Specified]

More Information

Certain Agreements

All 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.

Results Point of Contact

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Responsible Party: PRS Results Training
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