

Trial: CHDR1939-B

## 8.1 Study Participants and Safety Data

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**Table 8.1.1 Subject Disposition**

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Table 8.1.1 Subject Disposition

	Screened	Enrolled	Safety	Completed	PD
Frequency	17	17	16	15	16
Percent	100.0	100.0	94.1	88.2	94.1

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**Table 8.1.2 Subject Demographics**

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Table 8.1.2 Subject Demographics

All subjects	
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Age (years)	
N	16
Mean (SD)	17.4 (8.7)
Median	17
Min, Max	6, 33
Sex	
Female	11 (68.8%)
Male	5 (31.3%)
Race	
White	16 (100%)

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**Table 8.1.4.1 Summary of Number of TEAEs and Number and Percentage of Subjects with TEAEs by Treatment SOC and PT**

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Table 8.1.4.1 Summary of Number of TEAEs and Number of Subjects with TEAEs by Treatment SOC and PT

System Organ Class/ Preferred Term	Clonazepam (N=16)		Placebo (N=15)	
	Events N	Subjects N (%)	Events N	Subjects N (%)
ANY EVENTS	29	11 ( 68.8)	10	7 ( 46.7)
GASTROINTESTINAL DISORDERS	2	2 ( 12.5)	1	1 ( 6.7)
Abdominal pain upper	2	2 ( 12.5)	-	-
Nausea	-	-	1	1 ( 6.7)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	10	9 ( 56.3)	2	2 ( 13.3)
Fatigue	8	8 ( 50.0)	2	2 ( 13.3)
Feeling drunk	1	1 ( 6.3)	-	-
Paradoxical drug reaction	1	1 ( 6.3)	-	-
INFECTIONS AND INFESTATIONS	2	2 ( 12.5)	1	1 ( 6.7)
Corona virus infection	1	1 ( 6.3)	-	-
Nasopharyngitis	1	1 ( 6.3)	1	1 ( 6.7)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1	1 ( 6.3)	-	-
Head injury	1	1 ( 6.3)	-	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1	1 ( 6.3)	-	-
Bursitis	1	1 ( 6.3)	-	-
NERVOUS SYSTEM DISORDERS	9	4 ( 25.0)	4	4 ( 26.7)
Balance disorder	2	2 ( 12.5)	-	-
Disturbance in attention	1	1 ( 6.3)	-	-
Dysarthria	1	1 ( 6.3)	-	-
Headache	1	1 ( 6.3)	4	4 ( 26.7)

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Table 8.1.4.1 Summary of Number of TEAEs and Number of Subjects with TEAEs by Treatment SOC and PT

System Organ Class/ Preferred Term	Clonazepam (N=16)		Placebo (N=15)	
	Events N	Subjects N (%)	Events N	Subjects N (%)
Slow response to stimuli	1	1 ( 6.3)	-	-
Somnolence	3	1 ( 6.3)	-	-
PSYCHIATRIC DISORDERS	2	1 ( 6.3)	2	2 ( 13.3)
Bradyphrenia	-	-	1	1 ( 6.7)
Disinhibition	1	1 ( 6.3)	-	-
Impulse-control disorder	1	1 ( 6.3)	-	-
Inappropriate affect	-	-	1	1 ( 6.7)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	2	2 ( 12.5)	-	-
Oropharyngeal pain	1	1 ( 6.3)	-	-
Rhinorrhoea	1	1 ( 6.3)	-	-

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**Table 8.1.4.2 Summary of Number and Percentage of Subjects with TEAEs by Treatment, SOC, PT and Severity**

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Summary of number of subjects with TEAEs  
by treatment SOC PT and severity

System Organ Class/ Preferred Term	Clonazepam (N=16)			Placebo (N=15)		
	Mild N	Moderate N	Severe N	Mild N	Moderate N	Severe N
ANY EVENTS	10	2	-	7	-	-
GASTROINTESTINAL DISORDERS	1	1	-	1	-	-
Abdominal pain upper	1	1	-	-	-	-
Nausea	-	-	-	1	-	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	8	1	-	2	-	-
Fatigue	8	-	-	2	-	-
Feeling drunk	1	-	-	-	-	-
Paradoxical drug reaction	-	1	-	-	-	-
INFECTIONS AND INFESTATIONS	2	-	-	1	-	-
Corona virus infection	1	-	-	-	-	-
Nasopharyngitis	1	-	-	1	-	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1	-	-	-	-	-
Head injury	1	-	-	-	-	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1	-	-	-	-	-
Bursitis	1	-	-	-	-	-
NERVOUS SYSTEM DISORDERS	4	-	-	4	-	-
Balance disorder	2	-	-	-	-	-
Disturbance in attention	1	-	-	-	-	-
Dysarthria	1	-	-	-	-	-
Headache	1	-	-	4	-	-

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Summary of number of subjects with TEAEs  
by treatment SOC PT and severity

System Organ Class/ Preferred Term	Clonazepam (N=16)			Placebo (N=15)		
	Mild	Moderate	Severe	Mild	Moderate	Severe
	N	N	N	N	N	N
Slow response to stimuli	1	-	-	-	-	-
Somnolence	1	-	-	-	-	-
PSYCHIATRIC DISORDERS	1	-	-	2	-	-
Bradyphrenia	-	-	-	1	-	-
Disinhibition	1	-	-	-	-	-
Impulse-control disorder	1	-	-	-	-	-
Inappropriate affect	-	-	-	1	-	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	2	-	-	-	-	-
Oropharyngeal pain	1	-	-	-	-	-
Rhinorrhoea	1	-	-	-	-	-

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**Table 8.1.4.3 Summary of Number of subjects with TEAEs by treatment, SOC, PT and Drug Relatedness**

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Summary of number of subjects with TEAEs by treatment, SOC, PT and drug relatedness  
by treatment System Organ Class preferred term and relationship

System Organ Class/ Preferred Term	Clonazepam (N=16)				Placebo (N=15)			
	PROB	POS	UNL	UNR	PROB	POS	UNL	UNR
	N	N	N	N	N	N	N	N
ANY EVENTS	9	2	-	4	2	1	1	3
GASTROINTESTINAL DISORDERS	-	1	-	1	1	-	-	-
Abdominal pain upper	-	1	-	1	-	-	-	-
Nausea	-	-	-	-	1	-	-	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	8	1	-	-	2	-	-	-
Fatigue	7	1	-	-	2	-	-	-
Feeling drunk	1	-	-	-	-	-	-	-
Paradoxical drug reaction	1	-	-	-	-	-	-	-
INFECTIONS AND INFESTATIONS	-	-	-	2	-	-	-	1
Corona virus infection	-	-	-	1	-	-	-	-
Nasopharyngitis	-	-	-	1	-	-	-	1
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1	-	-	-	-	-	-	-
Head injury	1	-	-	-	-	-	-	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	-	-	-	1	-	-	-	-
Bursitis	-	-	-	1	-	-	-	-
NERVOUS SYSTEM DISORDERS	4	2	-	-	1	1	-	2
Balance disorder	2	-	-	-	-	-	-	-
Disturbance in attention	-	1	-	-	-	-	-	-
Dysarthria	1	-	-	-	-	-	-	-
Headache	1	-	-	-	1	1	-	2
Slow response to stimuli	1	-	-	-	-	-	-	-
Somnolence	1	1	-	-	-	-	-	-
PSYCHIATRIC DISORDERS	1	-	-	-	1	-	1	-
Bradyphrenia	-	-	-	-	1	-	-	-
Disinhibition	1	-	-	-	-	-	-	-
Impulse-control disorder	1	-	-	-	-	-	-	-

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Summary of number of subjects with TEAEs by treatment, SOC, PT and drug relatedness  
by treatment System Organ Class preferred term and relationship

System Organ Class/ Preferred Term	Clonazepam (N=16)				Placebo (N=15)			
	PROB	POS	UNL	UNR	PROB	POS	UNL	UNR
	N	N	N	N	N	N	N	N
Inappropriate affect	-	-	-	-	-	-	1	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	-	-	-	2	-	-	-	-
Oropharyngeal pain	-	-	-	1	-	-	-	-
Rhinorrhoea	-	-	-	1	-	-	-	-

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