EU Clinical Trials Register

Clinical trial results:
A Multicenter, Double-Blind, Randomized, Parallel-Group, Active- and Placebo-Controlled Polysomnography Study to Evaluate the Efficacy, Safety, and Tolerability of JNJ-42847922 in Subjects With Insomnia Disorder

Summary

EudraCT number	2017-000980-33
Trial protocol	DE BE PL FR
Global end of trial date	03 April 2019

Results information

Result version number	v1 (current)
This version publication date	16 April 2020
First version publication date	16 April 2020

Trial information

Trial identification

Sponsor protocol code	42847922ISM2005

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03375203
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen Research & Development, LLC
Sponsor organisation address	Turnhoutseweg 30, Beerse, Belgium, B-2340
Public contact	Clinical Registry Group, Janssen Research & Development, LLC, ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry Group, Janssen Research & Development, LLC, ClinicalTrialsEU@its.jnj.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	03 April 2019
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	03 April 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study was to assess the dose-response of 3 doses of seltorexant (5 milligram [mg], 10 mg, and 20 mg) compared to placebo on an objective measure of sleep onset in subjects with insomnia disorder.

Protection of trial subjects:

This study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with Good Clinical Practices and applicable regulatory requirements. Safety evaluations were based on adverse events, clinical laboratory tests (hematology, serum chemistry, and urinalysis), vital sign measurements, physical examinations, electrocardiogram (ECG), Cognitive assessment (modified Patient Reported Outcome Measurement Information System-Applied Cognition Abilities [PROMIS-ACA] and cognitive functioning evaluations), residual effects (Karolinska Sleepiness Scale [KSS], body sway), withdrawal effects (Physician Withdrawal Checklist [PWC], Benzodiazepine Withdrawal Symptom Questionnaire [BWSQ]), Columbia Suicide Severity Rating Scale (C-SSRS).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	16 November 2017
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Belgium: 9
Country: Number of subjects enrolled	Germany: 43
Country: Number of subjects enrolled	France: 1
Country: Number of subjects enrolled	Japan: 21
Country: Number of subjects enrolled	Poland: 5
Country: Number of subjects enrolled	United States: 285
Worldwide total number of subjects	364
EEA total number of subjects	58

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37	0

wk	
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	238
From 65 to 84 years	126
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Total of 365 subjects were randomized, 364 were treated. 1 subject was randomized in error group never received study drug, was discontinued from study. 1 subject was randomized to JNJ-42847922 10 mg group received 5 mg of JNJ-42847922 and was summarized under 5 mg group for safety analyses, and under 10 mg dose group for all other analyses.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Subjects received matching placebo as 2 oral capsules for 14 consecutive nights from Day 1 to Day 14.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Subjects received matching placebo as 2 oral capsules for 14 consecutive nights from Day 1 to Day 14.

Arm title	JNJ-42847922 5 mg

Arm description:

Subjects received JNJ-42847922 5 milligram (mg) dose as two 2.5 mg oral capsules for 14 consecutive nights from Day 1 to Day 14.

Arm type	Experimental
Investigational medicinal product name	JNJ-42847922
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Subjects received JNJ-42847922 5 milligram (mg) dose as two 2.5 mg oral capsules for 14 consecutive nights from Day 1 to Day 14.

Arm title	JNJ-42847922 10 mg

Arm description:

Subjects receive JNJ-42847922 10 mg as one 10 mg oral capsule and one placebo capsule for 14 consecutive nights from Day 1 to Day 14.

Arm type	Experimental

Investigational medicinal product name	JNJ-42847922
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Subjects receive JNJ-42847922 10 mg as one 10 mg oral capsule and one placebo oral capsule for 14 consecutive nights from Day 1 to Day 14.

Arm title	JNJ-42847922 20 mg

Arm description:

Subjects received JNJ-42847922 20 mg as one 20 mg oral capsule and one placebo capsule for 14 consecutive nights from Day 1 to Day 14.

Arm type	Experimental
Investigational medicinal product name	JNJ-42847922
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Subjects received JNJ-42847922 20 mg as one 20 mg oral capsule and one placebo oral capsule for 14 consecutive nights from Day 1 to Day 14.

Arm title	Zolpidem

Arm description:

Subjects received Zolpidem 5 mg as one 5 mg capsule plus one placebo capsule or 10 mg Zolpidem as two 5 mg oral capsules for 14 consecutive nights from Day 1 to Day 14.

Arm type	Active comparator
Investigational medicinal product name	Zolpidem
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Subjects received Zolpidem 5 mg as one 5 mg capsule and one placebo oral capsule, or 10 mg Zolpidem as two 5 mg oral capsules for 14 consecutive nights from Day 1 to Day 14.

Number of subjects in period 1	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg
Started	75	71	74
Completed	69	68	72
Not completed	6	3	2
Adverse event, non-fatal	2	3	-
Non-compliance with study drug	1	-	-
Adverse event, serious non-fatal	-	-	-
Withdrawal by subject	3	-	1
Protocol deviation	-	-	1

Number of subjects in period 1	JNJ-42847922 20 mg	Zolpidem
Started	71	73

Completed	69	69
Not completed	2	4
Adverse event, non-fatal	1	2
Non-compliance with study drug	-	-
Adverse event, serious non-fatal	1	-
Withdrawal by subject	-	2
Protocol deviation	-	-

Baseline characteristics

Reporting groups

Reporting group title	Placebo
Reporting group description:	
Subjects received matching placebo as 2 oral capsules for 14 consecutive nights from Day 1 to Day 14.	
Reporting group title	JNJ-42847922 5 mg
Reporting group description:	
Subjects received JNJ-42847922 5 milligram (mg) dose as two 2.5 mg oral capsules for 14 consecutive nights from Day 1 to Day 14.	
Reporting group title	JNJ-42847922 10 mg
Reporting group description:	
Subjects receive JNJ-42847922 10 mg as one 10 mg oral capsule and one placebo capsule for 14 consecutive nights from Day 1 to Day 14.	
Reporting group title	JNJ-42847922 20 mg
Reporting group description:	
Subjects received JNJ-42847922 20 mg as one 20 mg oral capsule and one placebo capsule for 14 consecutive nights from Day 1 to Day 14.	
Reporting group title	Zolpidem
Reporting group description:	
Subjects received Zolpidem 5 mg as one 5 mg capsule plus one placebo capsule or 10 mg Zolpidem as two 5 mg oral capsules for 14 consecutive nights from Day 1 to Day 14.	

Reporting group values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg
Number of subjects	75	71	74
Title for AgeCategorical			
Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	50	45	48
From 65 to 84 years	25	26	26
85 years and over	0	0	0
Title for AgeContinuous			
Units: years			
arithmetic mean	58.6	56.9	57.6
standard deviation	± 11.49	± 13.85	± 12.9
Title for Gender			
Units: subjects			
Female	45	48	51
Male	30	23	23

Reporting group values	JNJ-42847922 20 mg	Zolpidem	Total
Number of subjects	71	73	364
Title for AgeCategorical			
Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	47	48	238
From 65 to 84 years	24	25	126

85 years and over	0	0	0

Title for AgeContinuous			
Units: years			
arithmetic mean	57.6	58.5	
standard deviation	± 11.88	± 12.03	-
Title for Gender			
Units: subjects			
Female	50	52	246
Male	21	21	118

End points

End points reporting groups

Reporting group title	Placebo

Reporting group description:

Subjects received matching placebo as 2 oral capsules for 14 consecutive nights from Day 1 to Day 14.

Reporting group title	JNJ-42847922 5 mg

Reporting group description:

Subjects received JNJ-42847922 5 milligram (mg) dose as two 2.5 mg oral capsules for 14 consecutive nights from Day 1 to Day 14.

Reporting group title	JNJ-42847922 10 mg

Reporting group description:

Subjects receive JNJ-42847922 10 mg as one 10 mg oral capsule and one placebo capsule for 14 consecutive nights from Day 1 to Day 14.

Reporting group title	JNJ-42847922 20 mg

Reporting group description:

Subjects received JNJ-42847922 20 mg as one 20 mg oral capsule and one placebo capsule for 14 consecutive nights from Day 1 to Day 14.

Reporting group title	Zolpidem

Reporting group description:

Subjects received Zolpidem 5 mg as one 5 mg capsule plus one placebo capsule or 10 mg Zolpidem as two 5 mg oral capsules for 14 consecutive nights from Day 1 to Day 14.

Subject analysis set title	Placebo
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received matching placebo as 2 oral capsules for 14 consecutive nights from Day 1 to Day 14.

Subject analysis set title	JNJ-42847922 5 mg
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received JNJ-42847922 5 milligram (mg) dose as two 2.5 mg oral capsules for 14 consecutive nights from Day 1 to Day 14. One subject who was randomized to JNJ-42847922 10 mg dose group received 5 mg of JNJ-42847922. This subject is summarized under the 5 mg dose group for safety analyses.

Subject analysis set title	JNJ-42847922 10 mg
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects receive JNJ-42847922 10 mg as one 10 mg oral capsule and one placebo capsule for 14 consecutive nights from Day 1 to Day 14. One subject who was randomized to JNJ-42847922 10 mg dose group received 5 mg of JNJ-42847922. This subject is summarized under the 5 mg dose group for safety analyses.

Subject analysis set title	JNJ-42847922 20 mg
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received JNJ-42847922 20 mg as one 20 mg oral capsule and one placebo capsule for 14 consecutive nights from Day 1 to Day 14.

Subject analysis set title	Zolpidem
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received Zolpidem 5 mg as one 5 mg capsule plus one placebo capsule or 10 mg Zolpidem as two 5 mg oral capsules for 14 consecutive nights from Day 1 to Day 14.

Primary: Change from Baseline in Latency to Persistent Sleep (LPS) as Measured by Polysomnography (PSG) on Night 1

End point title	Change from Baseline in Latency to Persistent Sleep (LPS) as Measured by Polysomnography (PSG) on Night 1

End point description:

LPS was measured on Night 1 by PSG. LPS is the time in minutes from 'lights out' that marks the starting of total recording time to the first epoch scored as sleep. The LPS change from baseline on Night 1 was calculated as (LPS at Night 1 minus Baseline LPS). Negative changes in LPS indicated improvement. Full analysis set included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. Here, N (number of subjects analyzed) signifies number of subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Baseline and Night 1

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	75	71	73	71
Units: Minutes				
arithmetic mean (standard deviation)	-15.24 (± 78.547)	-29.92 (± 49.049)	-49.49 (± 53.216)	-47.69 (± 48.423)

End point values	Zolpidem			
Subject group type	Reporting group			
Number of subjects analysed	73			
Units: Minutes				
arithmetic mean (standard deviation)	-40.74 (± 54.395)			

Statistical analyses

Statistical analysis title	Stastistical Analysis 1
Comparison groups	JNJ-42847922 5 mg v Placebo
Number of subjects included in analysis	146
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.346
Method	ANCOVA
Parameter estimate	Back-transformed Least Square Mean Ratio
Point estimate	0.88
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.7
upper limit	1.1

Statistical analysis title	Stastistical Analysis 2
Comparison groups	Placebo v JNJ-42847922 10 mg
Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.001
Method	ANCOVA
Parameter estimate	Back-transformed Least Square Mean Ratio
Point estimate	0.64
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.51
upper limit	0.81

Statistical analysis title	Stastistical Analysis 3
Comparison groups	Placebo v JNJ-42847922 20 mg
Number of subjects included in analysis	146
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Back-transformed Least Square Mean Ratio
Point estimate	0.51
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.41
upper limit	0.64

Secondary: Change from Baseline in Wake After Sleep Onset (WASO) Over the First 6 Hours as Measured by PSG on Night 1

End point title	Change from Baseline in Wake After Sleep Onset (WASO) Over the First 6 Hours as Measured by PSG on Night 1

End point description:

Polysomnography was used to measure the time to wake after initial sleep onset over the first 6 hours (WASO-6) on Night 1 was reported. Negative changes in WASO-6 indicate improvement. Full analysis set included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. Here, N (number of subjects analyzed) signifies number of subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline and Night 1

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	74	71	73	71
Units: Minutes				
arithmetic mean (standard deviation)	-15.05 (± 57.485)	-22.70 (± 45.904)	-42.57 (± 40.011)	-44.69 (± 42.823)

End point values	Zolpidem			
Subject group type	Reporting group			
Number of subjects analysed	73			
Units: Minutes				
arithmetic mean (standard deviation)	-29.04 (± 46.779)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Latency to Persistent Sleep as Measured by PSG on Night 13

End point title	Change from Baseline in Latency to Persistent Sleep as Measured by PSG on Night 13

End point description:

LPS was measured on Night 13 by PSG. LPS is the time in minutes from 'lights out' that marks the starting of total recording time to the first epoch scored as sleep. Negative changes in LPS indicate improvement. Full analysis set included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. Here, N (number of subjects analyzed) signifies number of subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline and Night 13

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	69	69	73	69
Units: Minutes				
arithmetic mean (standard deviation)	-23.74 (± 61.790)	-27.12 (± 54.726)	-53.99 (± 60.292)	-41.19 (± 59.713)

End point values	Zolpidem			
Subject group type	Reporting group			
Number of subjects analysed	69			
Units: Minutes				
arithmetic mean (standard deviation)	-30.94 (± 60.236)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in WASO Over the First 6 Hours as Measured by PSG on Night 13

End point title	Change from Baseline in WASO Over the First 6 Hours as Measured by PSG on Night 13

End point description:

Polysomnography was used to measure the time to wake after initial sleep onset over the first 6 hours (WASO-6) on Night 13 was reported. Negative changes in WASO-6 indicate improvement. Full analysis set included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. Here, N (number of subjects analyzed) signifies number of subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline and Night 13

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	68	69	73	68
Units: Minutes				
arithmetic mean (standard deviation)	-17.80 (± 52.369)	-14.63 (± 57.207)	-30.74 (± 52.835)	-38.40 (± 53.661)

End point values	Zolpidem			
Subject group type	Reporting group			
Number of subjects analysed	69			
Units: Minutes				
arithmetic mean (standard deviation)	-20.22 (± 46.465)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Total Sleep Time (TST) as Measured by PSG Over 6 Hours on Nights 1 and 13

End point title	Change from Baseline in Total Sleep Time (TST) as Measured by PSG Over 6 Hours on Nights 1 and 13

End point description:

TST is defined as the total sleep time in minutes, the total sleep time is the total amount of sleep time scored during the total recording time. Positive changes in TST indicate improvement. Full analysis set included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. Here, N (number of subjects analyzed) signifies number of subjects evaluable for this endpoint. Here, 'n' (number analyzed) signifies number of subjects who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

Baseline, Nights 1 and 13

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	75	71	73	71
Units: Minutes				
arithmetic mean (standard deviation)				
Night 1 (n= 75, 71, 73, 71, 73)	25.50 (± 72.146)	43.26 (± 50.771)	76.47 (± 50.711)	80.49 (± 56.216)
Night 13 (n=69, 69, 73, 69, 69)	33.16 (± 71.488)	39.80 (± 66.556)	66.03 (± 62.995)	67.66 (± 66.254)

End point values	Zolpidem			
Subject group type	Reporting group			
Number of subjects analysed	73			
Units: Minutes				
arithmetic mean (standard deviation)				
Night 1 (n= 75, 71, 73, 71, 73)	53.70 (± 57.688)			
Night 13 (n=69, 69, 73, 69, 69)	35.84 (± 64.950)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Total Sleep Time (TST) as Measured by PSG Over 8 Hours on Nights 1 and 13

End point title	Change from Baseline in Total Sleep Time (TST) as Measured by PSG Over 8 Hours on Nights 1 and 13

End point description:

TST is defined as the total sleep time in minutes, the total sleep time is the total amount of sleep time scored during the total recording time. Positive changes in TST indicate improvement. Full analysis set included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. Here, N (number of subjects analyzed) signifies number of subjects evaluable for this endpoint. Here, 'n' (number analyzed) signifies number of subjects who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

Baseline, Nights 1 and 13

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	75	71	73	71
Units: Minutes				
arithmetic mean (standard deviation)				
Night 1 (n=75, 71, 73, 71, 73)	37.03 (± 86.539)	47.85 (± 64.499)	81.20 (± 60.607)	81.07 (± 71.581)
Night 13 (n=69, 69, 73, 69, 69)	38.45 (± 83.177)	45.72 (± 72.640)	64.84 (± 77.358)	64.27 (± 82.377)

End point values	Zolpidem			
Subject group type	Reporting group			
Number of subjects analysed	73			
Units: Minutes				
arithmetic mean (standard deviation)				
Night 1 (n=75, 71, 73, 71, 73)	63.88 (± 59.115)			
Night 13 (n=69, 69, 73, 69, 69)	39.26 (± 77.773)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Sleep Efficiency (SE) Measured by PSG on Nights 1 and 13

End point title	Change from Baseline in Sleep Efficiency (SE) Measured by PSG on Nights 1 and 13

End point description:

Sleep efficiency was measured as the total sleep time divided by the total time in bed (that is, the number of hours from the beginning of the Polysomnography recording to the end of the recording) (in percent). Positive changes in SE indicate improvement. Full analysis set included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. Here, N (number of subjects analyzed) signifies number of subjects evaluable for this endpoint. Here, 'n' (number analyzed) signifies number of subjects who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

Baseline, Nights 1 and 13

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	75	71	73	71
Units: Percent of efficient sleep				
arithmetic mean (standard deviation)				
Night 1 (n=75, 71, 73,71, 73)	7.74 (± 18.031)	10.18 (± 12.818)	16.92 (± 12.626)	16.86 (± 14.963)
Night 13 (n=69, 69, 73,69, 69)	7.99 (± 17.322)	9.51 (± 15.154)	13.67 (± 16.037)	13.56 (± 17.199)

End point values	Zolpidem			
Subject group type	Reporting group			
Number of subjects analysed	73			
Units: Percent of efficient sleep				
arithmetic mean (standard deviation)				
Night 1 (n=75, 71, 73,71, 73)	13.29 (± 12.317)			
Night 13 (n=69, 69, 73,69, 69)	8.27 (± 16.323)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Wake After Sleep Onset Total Score Measured Hourly on Day 1 and 13 from Hour 1 to Hour 8

End point title	Change from Baseline in Wake After Sleep Onset Total Score Measured Hourly on Day 1 and 13 from Hour 1 to Hour 8

End point description:

Polysomnography was used to measure the time to wake after initial sleep onset measured hourly on Day 1 and 13 from Hour 1 to Hour 8 was reported. WASO is measured during overnight sleep laboratory (PSG) assessment and defined as the duration of wakefulness from the onset of persistent sleep (that is, 10 consecutive minutes of sleep) over 8 hours of PSG assessment. Negative changes in WASO indicate improvement. Full analysis set included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. Here, N (number of subjects analyzed) signifies number of subjects evaluable for this endpoint. Here, 'n' (number analyzed) signifies number of subjects who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

Baseline, Day 1 and 13

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	74	71	73	71
Units: Minutes				
arithmetic mean (standard deviation)				
WASO (hour 1): Day 1(n=43, 43, 47, 50, 48)	-3.40 (± 13.074)	-3.55 (± 10.510)	-3.44 (± 12.969)	-6.37 (± 14.213)
WASO (hour 1): Day 13(n=42, 41, 46, 48, 45)	0.43 (± 12.083)	-4.78 (± 8.824)	-7.05 (± 14.569)	-7.47 (± 13.004)
WASO (hour 2): Day 1(n=66, 62, 66, 67, 64)	1.06 (± 18.481)	-5.72 (± 11.817)	-9.62 (± 16.721)	-10.82 (± 13.658)
WASO (hour 2):Day 13(n=61, 63, 67, 63, 59)	1.11 (± 18.504)	-4.12 (± 14.596)	-9.04 (± 17.034)	-9.64 (± 14.963)
WASO (hour 3): Day 1(n=69, 69, 72, 70, 71)	-5.57 (± 18.316)	-3.91 (± 12.037)	-11.05 (± 13.272)	-9.64 (± 13.055)
WASO (hour 3): Day 13(n=64, 67, 71, 67, 66)	-5.70 (± 17.681)	-0.31 (± 18.562)	-8.10 (± 12.446)	-6.99 (± 15.331)
WASO (hour 4): Day 1(n=72, 71, 72, 71, 72)	-5.33 (± 17.109)	-4.73 (± 13.193)	-9.67 (± 14.495)	-9.74 (± 14.727)
WASO (hour 4): Day 13(n=67, 69, 71, 68, 67)	-5.49 (± 18.185)	-3.47 (± 16.754)	-9.57 (± 14.483)	-6.21 (± 14.140)
WASO (hour 5): Day 1(n= 73, 71, 73, 71, 73)	-3.36 (± 22.284)	-6.16 (± 15.820)	-7.53 (± 14.371)	-7.44 (± 15.834)
WASO (hour 5): Day 13(n=68, 69, 73, 69, 69)	-4.96 (± 22.597)	-4.06 (± 20.776)	-5.34 (± 20.232)	-7.97 (± 17.016)
WASO (hour 6): Day 1(n=74, 71, 73, 71, 73)	-1.06 (± 17.258)	-4.46 (± 22.383)	-5.44 (± 17.510)	-7.78 (± 18.348)
WASO (hour 6): Day 13(n=68, 69, 73, 69, 69)	-4.69 (± 19.658)	-3.09 (± 21.426)	0.56 (± 22.721)	-7.37 (± 20.872)
WASO (hour 7): Day 1(n= 74, 71, 73,71, 73)	-5.01 (± 22.247)	-5.71 (± 19.784)	-3.84 (± 16.756)	-1.61 (± 19.349)
WASO (hour 7): Day 13(n=69, 69, 73,69, 69)	-3.57 (± 21.828)	-4.92 (± 18.271)	-1.50 (± 21.145)	1.16 (± 23.642)
WASO (hour 8): Day 1(n=74, 71, 73, 71, 73)	-7.52 (± 23.369)	0.66 (± 21.311)	-0.65 (± 22.278)	1.25 (± 22.046)
WASO (hour 8): Day 13(n=69, 69, 73, 69, 69)	-1.73 (± 24.898)	-0.63 (± 20.118)	1.88 (± 23.845)	1.24 (± 20.858)

End point values	Zolpidem			
Subject group type	Reporting group			
Number of subjects analysed	73			
Units: Minutes				
arithmetic mean (standard deviation)				
WASO (hour 1): Day 1(n=43, 43, 47, 50, 48)	-5.40 (± 12.086)			
WASO (hour 1): Day 13(n=42, 41, 46, 48, 45)	-4.90 (± 11.821)			
WASO (hour 2): Day 1(n=66, 62, 66, 67, 64)	-7.68 (± 14.812)			
WASO (hour 2):Day 13(n=61, 63, 67, 63, 59)	-4.37 (± 16.883)			
WASO (hour 3): Day 1(n=69, 69, 72, 70, 71)	-9.62 (± 14.141)			
WASO (hour 3): Day 13(n=64, 67, 71, 67, 66)	-5.12 (± 18.140)			

WASO (hour 4): Day 1(n=72, 71, 72, 71, 72)	-6.23 (± 16.471)			
WASO (hour 4): Day 13(n=67, 69, 71, 68, 67)	-7.00 (± 15.727)			
WASO (hour 5): Day 1(n= 73, 71, 73, 71, 73)	-4.34 (± 16.150)			
WASO (hour 5): Day 13(n=68, 69, 73, 69, 69)	-5.03 (± 16.306)			
WASO (hour 6): Day 1(n=74, 71, 73, 71, 73)	-1.46 (± 19.965)			
WASO (hour 6): Day 13(n=68, 69, 73, 69, 69)	0.84 (± 20.768)			
WASO (hour 7): Day 1(n= 74, 71, 73,71, 73)	-6.15 (± 13.756)			
WASO (hour 7): Day 13(n=69, 69, 73,69, 69)	-0.75 (± 18.096)			
WASO (hour 8): Day 1(n=74, 71, 73, 71, 73)	-3.95 (± 20.149)			
WASO (hour 8): Day 13(n=69, 69, 73, 69, 69)	-3.22 (± 22.343)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Number of Nighttime Awakenings (nNAW) Over 6 Hours on Day 1 and 13

End point title	Change from Baseline in Number of Nighttime Awakenings (nNAW) Over 6 Hours on Day 1 and 13

End point description:

PSG was used to measure the number of nighttime awakening over the first 6 hours after initial sleep onset. Negative changes in nNAW indicate improvement. FAS included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. Here, N (number of subjects analyzed) signifies number of subjects evaluable for this endpoint. Here, 'n' (number analyzed) signifies number of subjects who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

Baseline, Day 1 and 13

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	74	71	73	71
Units: Number of awakenings				
arithmetic mean (standard deviation)				
Day 1 (n=74, 71, 73, 71, 73)	-2.08 (± 6.412)	-0.87 (± 7.224)	0.14 (± 7.385)	-0.94 (± 9.102)
Day 13 (n=69, 69, 73, 69, 69)	-2.02 (± 6.928)	0.93 (± 7.769)	-0.40 (± 8.352)	-2.13 (± 7.542)

End point values	Zolpidem			
Subject group type	Reporting group			
Number of subjects analysed	73			
Units: Number of awakenings				
arithmetic mean (standard deviation)				
Day 1 (n=74, 71, 73, 71, 73)	-1.14 (± 8.727)			
Day 13 (n=69, 69, 73, 69, 69)	-0.57 (± 7.803)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Wake During Total Sleep Period on Day 1 and 13

End point title	Change from Baseline in Wake During Total Sleep Period on Day 1 and 13

End point description:

PSG was used to measure wake time during the total recording period. Negative changes in wake during total sleep period indicate improvement. Full analysis set included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. Here, N (number of subjects analyzed) signifies number of subjects evaluable for this endpoint. Here, 'n' (number analyzed) signifies number of subjects who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

Baseline, Day 1 and 13

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	74	71	73	71
Units: Minutes				
arithmetic mean (standard deviation)				
Day 1(n=74, 71, 73, 71, 73)	-13.79 (± 63.082)	-27.47 (± 58.188)	-49.64 (± 47.106)	-52.25 (± 40.828)
Day 13(n= 69, 69, 73, 69,69)	-18.83 (± 59.005)	-19.79 (± 60.626)	-42.57 (± 53.867)	-41.95 (± 64.846)

End point values	Zolpidem			
Subject group type	Reporting group			
Number of subjects analysed	73			
Units: Minutes				
arithmetic mean (standard deviation)				
Day 1(n=74, 71, 73, 71, 73)	-32.36 (± 53.737)			

Day 13(n= 69, 69, 73, 69,69)	-20.58 (± 56.799)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Wake After Final Awakening on Day 1 and 13

End point title	Change from Baseline in Wake After Final Awakening on Day 1 and 13

End point description:

Polysomnography was used to measure the time awake after final awakening to the end of the PSG period. Negative changes in wake after final awakening indicate improvement. FAS included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. Here, N (number of subjects analyzed) signifies number of subjects evaluable for this endpoint. Here, 'n' (number analyzed) signifies number of subjects who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

Baseline, Day 1 and 13

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	74	71	73	71
Units: Minutes				
arithmetic mean (standard deviation)				
Day 1(n=74, 71, 73, 71, 73)	-13.63 (± 50.958)	-0.28 (± 29.552)	2.80 (± 38.492)	7.21 (± 45.189)
Day 13(n=69, 69, 73, 69, 69)	-5.32 (± 55.112)	-0.39 (± 31.519)	12.42 (± 62.515)	5.62 (± 48.641)

End point values	Zolpidem			
Subject group type	Reporting group			
Number of subjects analysed	73			
Units: Minutes				
arithmetic mean (standard deviation)				
Day 1(n=74, 71, 73, 71, 73)	-5.40 (± 29.473)			
Day 13(n=69, 69, 73, 69, 69)	-2.17 (± 29.376)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Number of Nighttime Awakenings per hour (nNAW/hr) on Day 1 and 13

End point title	Change from Baseline in Number of Nighttime Awakenings per hour (nNAW/hr) on Day 1 and 13
End point description:	
PSG was used to measure number of nighttime awakenings per hour. Negative changes in nNAW/hr indicate improvement. FAS included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. Here, N (number of subjects analyzed) signifies number of subjects evaluable for this endpoint. Here, 'n' (number analyzed) signifies number of subjects who were evaluable at specified time points.	
End point type	Secondary
End point timeframe:	
Baseline, Day 1 and 13	

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	74	71	73	71
Units: Minutes				
arithmetic mean (standard deviation)				
Day 1(n=74, 71, 73, 71, 73)	-0.35 (± 1.069)	-0.14 (± 1.204)	0.02 (± 1.231)	-0.16 (± 1.517)
Day 13(n=69, 69, 73, 69, 69)	-0.34 (± 1.155)	0.16 (± 1.295)	-0.07 (± 1.392)	-0.36 (± 1.257)

End point values	Zolpidem			
Subject group type	Reporting group			
Number of subjects analysed	73			
Units: Minutes				
arithmetic mean (standard deviation)				
Day 1(n=74, 71, 73, 71, 73)	-0.19 (± 1.455)			
Day 13(n=69, 69, 73, 69, 69)	-0.10 (± 1.300)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Time to First Awakening After Sleep on Day 1 and 13

End point title	Change from Baseline in Time to First Awakening After Sleep on Day 1 and 13
End point description:	
PSG was used to measure the time to first awakening after sleep onset. Positive changes in time to first	

awakening after sleep indicate improvement. FAS included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. Here, N (number of subjects analyzed) signifies number of subjects evaluable for this endpoint. Here, 'n' (number analyzed) signifies number of subjects who were evaluable at specified time points.

End point type	Secondary

End point timeframe:	

Baseline, Day 1 and 13

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	74	71	73	70
Units: Minutes				
arithmetic mean (standard deviation)				
Day 1(n=74, 71, 73, 70, 73)	12.05 (± 57.535)	10.71 (± 61.015)	23.11 (± 73.749)	53.90 (± 92.802)
Day 13(n=69, 69, 71, 68, 67)	11.08 (± 45.714)	32.13 (± 70.549)	33.12 (± 71.826)	48.92 (± 88.909)

End point values	Zolpidem			
Subject group type	Reporting group			
Number of subjects analysed	73			
Units: Minutes				
arithmetic mean (standard deviation)				
Day 1(n=74, 71, 73, 70, 73)	35.63 (± 74.617)			
Day 13(n=69, 69, 71, 68, 67)	27.55 (± 75.080)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Rapid Eye Movement (REM) duration on Day 1 and 13

End point title	Change from Baseline in Rapid Eye Movement (REM) duration on Day 1 and 13

End point description:

PSG was used to measure REM duration (time to first REM period from sleep onset). FAS included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. Here, N (number of subjects analyzed) signifies number of subjects evaluable for this endpoint. Here, 'n' (number analyzed) signifies number of subjects who were evaluable at specified time points.

End point type	Secondary

End point timeframe:	

Baseline, Day 1 and 13

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	74	71	73	71
Units: Minutes				
arithmetic mean (standard deviation)				
Day 1(n=74, 71, 73, 71, 73)	10.32 (± 24.366)	10.23 (± 28.891)	25.12 (± 29.495)	23.79 (± 31.175)
Day 13(n=69, 69, 73, 69, 69)	5.70 (± 29.875)	6.40 (± 25.188)	17.42 (± 28.699)	12.91 (± 32.051)

End point values	Zolpidem			
Subject group type	Reporting group			
Number of subjects analysed	73			
Units: Minutes				
arithmetic mean (standard deviation)				
Day 1(n=74, 71, 73, 71, 73)	5.41 (± 22.381)			
Day 13(n=69, 69, 73, 69, 69)	5.97 (± 28.811)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Rapid Eye Movement Latency on Day 1 and 13

End point title	Change from Baseline in Rapid Eye Movement Latency on Day 1 and 13

End point description:

PSG was used to measure the REM latency. FAS included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. Here, N (number of subjects analyzed) signifies number of subjects evaluable for this endpoint. Here, 'n' (number analyzed) signifies number of subjects who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

Baseline, Day 1 and 13

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	73	70	73	70
Units: Minute				
arithmetic mean (standard deviation)				
Day 1 (n=73,70, 73, 70, 72)	-26.60 (± 82.487)	-38.06 (± 79.396)	-85.61 (± 84.380)	-88.36 (± 76.551)
Day 13 (n=67, 67, 72, 67, 67)	-26.41 (± 87.903)	-32.11 (± 86.623)	-83.89 (± 83.313)	-73.40 (± 81.747)

End point values	Zolpidem			
Subject group type	Reporting group			
Number of subjects analysed	72			
Units: Minute				
arithmetic mean (standard deviation)				
Day 1 (n=73,70, 73, 70, 72)	-42.73 (± 67.024)			
Day 13 (n=67, 67, 72, 67, 67)	-31.59 (± 64.953)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Sleep-Onset Rapid Eye Movement on Day 1 and 13

End point title	Percentage of Subjects with Sleep-Onset Rapid Eye Movement on Day 1 and 13

End point description:

PSG was used to measure the sleep-onset REM in subjects. REM sleep periods within 15 minutes from sleep onset were measured. FAS included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. Here, N (number of subjects analyzed) signifies number of subjects evaluable for this endpoint. Here, 'n' (number analyzed) signifies number of subjects who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

Day 1 and 13

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	75	71	73	71
Units: Percentage of subjects				
number (not applicable)				
Day 1 (n=75, 71, 73, 71, 73)	1.3	4.2	9.6	14.1
Day 13 (n=69, 69, 73, 69, 69)	1.4	2.9	4.1	8.7

End point values	Zolpidem			
Subject group type	Reporting group			
Number of subjects analysed	73			
Units: Percentage of subjects				
number (not applicable)				
Day 1 (n=75, 71, 73, 71, 73)	0			
Day 13 (n=69, 69, 73, 69, 69)	2.9			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Number of Sleep Cycles on Day 1 and 13

End point title	Change from Baseline in Number of Sleep Cycles on Day 1 and 13
End point description:	

PSG was used to measure the number of sleep cycles. FAS included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. Here, N (number of subjects analyzed) signifies number of subjects evaluable for this endpoint. Here, 'n' (number analyzed) signifies number of subjects who were evaluable at specified time points.

End point type	Secondary
End point timeframe:	

Baseline, Day 1 and 13

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	75	71	73	71
Units: Number of sleep cycles				
arithmetic mean (standard deviation)				
Day 1 (n=75, 71, 73, 71, 73)	0.43 (± 1.138)	0.40 (± 1.006)	0.97 (± 1.049)	0.75 (± 1.155)
Day 13 (n=69, 69, 73, 69, 69)	0.20 (± 1.222)	0.41 (± 1.062)	0.77 (± 1.182)	0.45 (± 1.219)

End point values	Zolpidem			
Subject group type	Reporting group			
Number of subjects analysed	73			
Units: Number of sleep cycles				
arithmetic mean (standard deviation)				
Day 1 (n=75, 71, 73, 71, 73)	0.62 (± 0.941)			
Day 13 (n=69, 69, 73, 69, 69)	0.32 (± 0.955)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Total Time Spent in Non-Rapid Eye Movement Sleep Stages N1, N2 and N3 on Day 1 and 13

End point title	Change from Baseline in Total Time Spent in Non-Rapid Eye Movement Sleep Stages N1, N2 and N3 on Day 1 and 13

End point description:

PSG was used to measure total time spent in non-rapid eye movement sleep stages N1, N2 and N3. Positive changes in NREM (total of N1-N3) duration indicate improvement. FAS included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. Here, N (number of subjects analyzed) signifies number of subjects evaluable for this endpoint. Here, 'n' (number analyzed) signifies number of subjects who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

Baseline, Day 1 and 13

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	75	71	73	71
Units: Minutes				
arithmetic mean (standard deviation)				
Day 1 (n= 75, 71, 73, 71, 73)	27.87 (± 68.202)	37.62 (± 49.817)	56.08 (± 45.218)	57.29 (± 54.245)
Day 13 (n=69, 69, 73, 69, 69)	32.74 (± 61.726)	39.33 (± 61.524)	47.41 (± 59.791)	51.37 (± 59.310)

End point values	Zolpidem			
Subject group type	Reporting group			
Number of subjects analysed	73			
Units: Minutes				
arithmetic mean (standard deviation)				
Day 1 (n= 75, 71, 73, 71, 73)	58.47 (± 52.803)			
Day 13 (n=69, 69, 73, 69, 69)	33.28 (± 62.466)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Subjective Sleep Parameters Using Consensus Sleep Diary - Morning Administration (CSD-M) on Days 2 and 14: Self-Reported Sleep-Onset Latency (sSOL), Subjective Wake After Sleep Onset (sWASO), Subjective Total Sleep Time (sTST)

End point title	Change from Baseline in Subjective Sleep Parameters Using Consensus Sleep Diary - Morning Administration (CSD-M) on Days 2 and 14: Self-Reported Sleep-Onset Latency (sSOL), Subjective Wake After Sleep Onset (sWASO), Subjective Total Sleep Time (sTST)

End point description:

CSD-M is a standardized subject diary based on expert consensus and qualitative subject input to retrieve patient reported subjective sleep parameters related to prior night's sleep. It allows for calculation of total time spent in bed and SE (as % of time asleep out of amount of time spent in bed). Sleep quality and how well rested subject felt at awaking are rated on a 5-point Likert scale ranges from 1 (very poor) to 5 (very good). Higher ratings indicate better sleep quality and more refreshing/restorative quality of sleep. CSD-M parameters analyzed includes: sSOL, sTST, sWASO. Negative change in sSOL, sWASO indicate improvement. Positive change in sTST indicates improvement. FAS included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. Here, N (number of subjects analyzed) signifies number of subjects evaluable for this endpoint and 'n' (number analyzed) signifies number of subjects who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

Baseline, Days 2 and 14

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	71	66	68	69
Units: Minutes				
arithmetic mean (standard deviation)				
sSOL: Day 2 (n=71, 66, 68, 69, 68)	15.20 (± 61.761)	-3.99 (± 46.858)	-16.49 (± 42.699)	-27.60 (± 34.456)
sSOL: Day 14 (n=63, 64, 67, 65, 66)	10.92 (± 68.201)	-8.81 (± 45.936)	-31.33 (± 36.888)	-33.93 (± 37.274)
sWASO: Day 2 (n=69, 64, 68, 64, 61)	0.81 (± 75.475)	-5.47 (± 61.067)	-18.54 (± 51.301)	-13.28 (± 48.225)
sWASO : Day 14(n= 59, 61, 64, 62, 60)	-5.60 (± 55.955)	-18.25 (± 56.719)	-25.20 (± 58.872)	-20.16 (± 65.568)
sTST: Day 2 (n=71, 66, 68, 69, 68)	-12.64 (± 96.051)	4.90 (± 92.105)	29.25 (± 67.934)	34.50 (± 76.904)
sTST: Day 14 (n=63, 64, 67, 65, 66)	3.30 (± 89.019)	29.34 (± 83.772)	36.79 (± 88.379)	45.35 (± 81.983)

End point values	Zolpidem			
Subject group type	Reporting group			
Number of subjects analysed	68			
Units: Minutes				
arithmetic mean (standard deviation)				

sSOL: Day 2 (n=71, 66, 68, 69, 68)	-24.98 (± 30.395)
sSOL: Day 14 (n=63, 64, 67, 65, 66)	-14.53 (± 53.705)
sWASO: Day 2 (n=69, 64, 68, 64, 61)	-15.99 (± 84.549)
sWASO : Day 14(n= 59, 61, 64, 62, 60)	-17.56 (± 51.007)
sTST: Day 2 (n=71, 66, 68, 69, 68)	37.07 (± 71.297)
sTST: Day 14 (n=63, 64, 67, 65, 66)	27.68 (± 90.387)

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Subjective Sleep Parameters Using Consensus Sleep Diary - Morning Administration (CSD-M) on Days 2 and 14: Subjective Refreshed Feeling on Waking (sFRESH) and Subjective Quality of Sleep (sQUAL)

End point title	Change from Baseline in Subjective Sleep Parameters Using Consensus Sleep Diary - Morning Administration (CSD-M) on Days 2 and 14: Subjective Refreshed Feeling on Waking (sFRESH) and Subjective Quality of Sleep (sQUAL)

End point description:

The CSD-M is a standardized subject diary based on expert consensus and qualitative subject input to retrieve patient reported subjective sleep parameters related to the prior night's sleep. It allows for calculation of total time spent in bed and SE (as the percentage of time asleep out of amount of time spent in bed). Sleep quality and how well rested subjects felt at awaking are rated on a 5-point Likert scale ranging from 1 (very poor) to (very good). Higher ratings indicate better sleep quality and more refreshing/restorative quality of sleep. CSD-M parameters analyzed includes: sFRESH and sQUAL. Positive change in sFRESH and sQUAL indicates improvement. Full analysis set included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. Here, N (number of subjects analyzed) signifies number of subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline, Day 2 and 14

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	71	66	68	69
Units: Units on a Scale				
arithmetic mean (standard deviation)				
sFRESH: Day 2 (n=71, 66, 68, 69, 68)	0.07 (± 0.930)	0.14 (± 0.865)	0.34 (± 0.852)	0.58 (± 1.050)
sFRESH: Day 14 (n=63, 64, 67, 65, 66)	0.26 (± 0.826)	0.39 (± 1.081)	0.51 (± 1.005)	0.59 (± 1.018)
sQUAL: Day 2 (n=71, 66, 68, 69, 68)	0.11 (± 0.995)	0.14 (± 1.054)	0.49 (± 0.896)	0.49 (± 1.091)
sQUAL: Day 14 (n=63, 64, 67, 65, 66)	0.26 (± 1.024)	0.43 (± 1.172)	0.79 (± 1.189)	0.67 (± 1.159)

End point values	Zolpidem			
Subject group type	Reporting group			
Number of subjects analysed	68			
Units: Units on a Scale				
arithmetic mean (standard deviation)				
sFRESH: Day 2 (n=71, 66, 68, 69, 68)	0.41 (± 0.876)			
sFRESH: Day 14 (n=63, 64, 67, 65, 66)	0.41 (± 1.051)			
sQUAL: Day 2 (n=71, 66, 68, 69, 68)	0.66 (± 0.818)			
sQUAL: Day 14 (n=63, 64, 67, 65, 66)	0.52 (± 1.084)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Subjective Sleep Parameters Using Consensus Sleep Diary - Morning Administration (CSD-M) on Days 2 and 14: Number of Nighttime Awakenings (s-nNAW)

End point title	Change from Baseline in Subjective Sleep Parameters Using Consensus Sleep Diary - Morning Administration (CSD-M) on Days 2 and 14: Number of Nighttime Awakenings (s-nNAW)

End point description:

CSD-M is a standardized participant diary based on expert consensus and qualitative participant input to retrieve patient reported subjective sleep parameters related to the prior night's sleep. It allows for calculation of total time spent in bed and SE (as the percentage of time asleep out of amount of time spent in bed). Sleep quality and how well rested participants felt at awaking are rated on a 5-point Likert scale ranging from 1 (very poor) to 5 (very good). Higher ratings indicate better sleep quality and more refreshing/restorative quality of sleep. CSD-M parameters analyzed include: s-nNAW. Negative change in s-nNAW indicate improvement. FAS included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. Here, N (number of subjects analyzed) signifies number of subjects evaluable for this endpoint. Here, 'n' (number analyzed) signifies number of subjects who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

Baseline, Day 2 and 14

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	71	66	68	69
Units: Number of awakenings				
arithmetic mean (standard deviation)				
Day 2 (n=71, 66, 68, 69, 68)	0.64 (± 2.197)	0.21 (± 1.465)	0.49 (± 1.465)	0.27 (± 1.418)
Day 14 (n=63, 64, 67, 65, 66)	0.10 (± 1.234)	0.04 (± 1.580)	0.05 (± 1.320)	-0.02 (± 1.175)

End point values	Zolpidem			

Subject group type	Reporting group			
Number of subjects analysed	68			
Units: Number of awakenings				
arithmetic mean (standard deviation)				
Day 2 (n=71, 66, 68, 69, 68)	0.38 (± 6.076)			
Day 14 (n=63, 64, 67, 65, 66)	-0.22 (± 1.376)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Sleep Disturbance as Measured by Patient Reported Outcome Measurement Information System – Sleep Disturbance (PROMIS-SD) Total Score on Days 8 and 14

End point title	Change from Baseline in Sleep Disturbance as Measured by Patient Reported Outcome Measurement Information System – Sleep Disturbance (PROMIS-SD) Total Score on Days 8 and 14

End point description:

PROMIS Sleep Disturbance (PROMIS-SD) Short Form subscale consists of a static 8-item questionnaire. Using a recall period of the past 7 days, it assesses the concepts of sleep initiation (2 items), quality of sleep (3 items), early morning feelings (2 items) and worrying about sleep (1 item). Each question has 5 response options ranging in value from 1-5. To find the total raw score for a short form with all questions answered, sum the values of the response to each question. For the 8-item form, the lowest possible raw score is 8; the highest possible raw score is 40. Lower scores indicate less sleep disturbance. Negative changes in scores indicate improvement. FAS included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. Here, N (number of subjects analyzed) signifies number of subjects evaluable for this endpoint. Here, 'n' (number analyzed) signifies number of subjects who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

Baseline, Days 8 and 14

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	63	60	66	63
Units: Unit on a Scale				
arithmetic mean (standard deviation)				
Day 8 (n=59, 55, 59, 58, 58)	-4.9 (± 6.81)	-9.0 (± 7.13)	-9.2 (± 7.17)	-9.6 (± 8.16)
Day 14 (n=63, 60, 66, 63, 66)	-5.7 (± 7.75)	-10.8 (± 7.64)	-10.3 (± 7.39)	-9.5 (± 7.93)

End point values	Zolpidem			
Subject group type	Reporting group			
Number of subjects analysed	66			
Units: Unit on a Scale				
arithmetic mean (standard deviation)				

Day 8 (n=59, 55, 59, 58, 58)	-8.3 (± 7.31)	
Day 14 (n=63, 60, 66, 63, 66)	-10.1 (± 8.06)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Impairment as Measured by Patient Reported Outcome Measurement Information System – Sleep Related Impairment (PROMIS-SRI) Total Score on Days 8 and 14

End point title	Change from Baseline in Impairment as Measured by Patient Reported Outcome Measurement Information System – Sleep Related Impairment (PROMIS-SRI) Total Score on Days 8 and 14

End point description:

PROMIS for Sleep Related Impairment (PROMIS-SRI) scale consists of 8 items to evaluated daytime consequences on functioning on 5-point Likert scales. PROMIS-SRI measures self-reported perceptions of alertness, sleepiness, and tiredness during usual waking hours, and perceived functional impairments during wakefulness associated with sleep problems or impaired alertness. Each question has five response options ranging in value from 1-5. To find total raw score for a short form with all questions answered, sum values of response to each question. For 8-item form, lowest possible raw score is 8; highest possible raw score is 40. Higher score indicates greater sleep impairment. FAS included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. Here, N (number of subjects analyzed) signifies number of subjects evaluable for this endpoint. Here, 'n' (number analyzed) signifies number of subjects who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

Baseline, Days 8 and 14

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	61	59	63	62
Units: Unit on a Scale				
arithmetic mean (standard deviation)				
Day 8 (n=57, 54, 55, 51, 54)	-4.0 (± 6.56)	-7.0 (± 6.15)	-5.5 (± 6.55)	-8.8 (± 7.09)
Day 14 (n=61, 59, 63, 62, 65)	-5.2 (± 6.88)	-9.1 (± 6.53)	-6.3 (± 6.94)	-7.8 (± 6.98)

End point values	Zolpidem			
Subject group type	Reporting group			
Number of subjects analysed	65			
Units: Unit on a Scale				
arithmetic mean (standard deviation)				
Day 8 (n=57, 54, 55, 51, 54)	-4.9 (± 6.98)			
Day 14 (n=61, 59, 63, 62, 65)	-7.4 (± 6.35)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Subjects's Assessment of Insomnia Severity Using the Patient Global Impression - Severity (PGI-S) Scale on Day 14

End point title	Change from Baseline in Subjects's Assessment of Insomnia Severity Using the Patient Global Impression - Severity (PGI-S) Scale on Day 14

End point description:

The PGI-S is a self-report scale to measure severity of illness (1=no insomnia, 2=very mild, 3=mild, 4=moderate, 5=severe, 6=very severe). Considering all aspects of insomnia, subjects were rated their severity on the PGI-S scale. Negative changes in scores indicate improvement. FAS included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. Here, N (number of subjects analyzed) signifies number of subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline and Day 14

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	59	59	65	62
Units: Unit on a Scale				
median (full range (min-max))	0.00 (-5.0 to 2.0)	-1.00 (-4.0 to 2.0)	-1.00 (-4.0 to 1.0)	-1.00 (-5.0 to 1.0)

End point values	Zolpidem			
Subject group type	Reporting group			
Number of subjects analysed	65			
Units: Unit on a Scale				
median (full range (min-max))	-1.00 (-4.0 to 1.0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Subject's Assessment of Improvement in Insomnia Using the Patient Global Impression - Improvement (PGI-I) Scale on Day

14

End point title	Change from Baseline in Subject's Assessment of Improvement in Insomnia Using the Patient Global Impression - Improvement (PGI-I) Scale on Day 14

End point description:

PGI-I is a self-report scale to measure improvement in illness (1=very much improved, 2=much improved, 3=improved [just enough to make a difference], 4=no change, 5=worse [just enough to make a difference], 6=much worse, 7=very much worse). Negative changes in scores indicate improvement. FAS included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. Here, N (number of subjects analyzed) signifies number of subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline and Day 14

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	62	69	65
Units: Units on a Scale				
median (full range (min-max))	3.00 (0.0 to 5.0)	2.00 (0.0 to 5.0)	2.00 (0.0 to 4.0)	2.00 (0.0 to 4.0)

End point values	Zolpidem			
Subject group type	Reporting group			
Number of subjects analysed	67			
Units: Units on a Scale				
median (full range (min-max))	2.00 (0.0 to 5.0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved Response During on Insomnia Severity Index (ISI) Total Score on Day 14

End point title	Percentage of Subjects Who Achieved Response During on Insomnia Severity Index (ISI) Total Score on Day 14

End point description:

Percentage (%) of Responders defined as at least 50% reduction from baseline in ISI total score were reported. It is a 7-item questionnaire assessing nature, severity, impact of insomnia. Dimensions evaluated are: severity of sleep onset, sleep maintenance, early morning awakening problems; sleep dissatisfaction; interference of sleep problem with daytime functioning; noticeability of sleep problems; distress caused by sleep difficulties. 5-point Likert scale (0-4) was used to rate each item, total score ranges from 0-28. Negative changes in scores indicate improvement. Total score interpreted insomnia as follows: absence (0-7); sub-threshold (8-14); moderate (15-21); severe (22-28). FAS included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. Subjects with missing values at a given time point are imputed as non-responders for that time point.

End point type	Secondary

End point timeframe:

Day 14

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	75	71	74	71
Units: Percentage of subjects				
number (not applicable)	21.3	40.8	31.1	33.8

End point values	Zolpidem			
Subject group type	Reporting group			
Number of subjects analysed	73			
Units: Percentage of subjects				
number (not applicable)	41.1			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved Response During on Insomnia Severity Index (ISI) Total Score on Day 14 – Observed Case

End point title	Percentage of Subjects Who Achieved Response During on Insomnia Severity Index (ISI) Total Score on Day 14 – Observed Case

End point description:

% of Responders defined as at least 50% reduction from baseline in ISI total score were reported. It is a 7-item questionnaire assessing nature, severity, impact of insomnia. Dimensions evaluated: severity of sleep onset, sleep maintenance, early morning awakening problems; sleep dissatisfaction; interference of sleep problem with daytime functioning; noticeability of sleep problems; distress caused by sleep difficulties. 5-point Likert scale (0-4) was used to rate each item, total score ranges from 0-28. Negative changes in scores indicate improvement. Total score interpreted insomnia as follows: absence (0-7); sub-threshold (8-14); moderate (15-21); severe (22-28). FAS included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. Here, N (number of subjects analyzed) signifies number subjects evaluable for this endpoint. Subjects with missing values at a given time point are excluded from frequency calculation for that time point.

End point type	Secondary

End point timeframe:

Day 14

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	69	69	73	69
Units: Percentage of Subjects				
number (not applicable)	23.2	42.0	31.5	34.8

End point values	Zolpidem			
Subject group type	Reporting group			
Number of subjects analysed	70			
Units: Percentage of Subjects				
number (not applicable)	42.9			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved Remission During on Insomnia Severity Index (ISI) Total Score on Day 14

End point title	Percentage of Subjects Who Achieved Remission During on Insomnia Severity Index (ISI) Total Score on Day 14

End point description:

Percentage of subjects with remission of insomnia symptom defined as, total score of less than or equal to (<=) 10 on ISI scale. ISI is a 7-item questionnaire assessing nature, severity, impact of insomnia. Dimensions evaluated are: severity of sleep onset, sleep maintenance, early morning awakening problems; sleep dissatisfaction; interference of sleep problem with daytime functioning; noticeability of sleep problems by others; distress caused by sleep difficulties. A 5-point Likert scale (0-4) is used to rate each item, yielding a total score ranging from 0 to 28. The total score is interpreted as follows: absence of insomnia (0-7); sub-threshold insomnia (8-14); moderate insomnia (15-21); and severe insomnia (22-28). Negative changes in scores indicate improvement. FAS included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. Subjects with missing values at a given time point are imputed as non-remitters for that time point.

End point type	Secondary

End point timeframe:

Day 14

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	75	71	74	71
Units: Percentage of subjects				
number (not applicable)	22.7	42.3	36.5	38.0

End point values	Zolpidem			

Subject group type	Reporting group			
Number of subjects analysed	73			
Units: Percentage of subjects				
number (not applicable)	47.9			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved Remission During on Insomnia Severity Index (ISI) Total Score on Day 14 – Observed Case

End point title	Percentage of Subjects Who Achieved Remission During on Insomnia Severity Index (ISI) Total Score on Day 14 – Observed Case

End point description:

% of subjects with remission of insomnia symptom defined as, total score of <= 10 on ISI scale. ISI is 7-item questionnaire assessing nature, severity, impact of insomnia. Dimensions evaluated are: severity of sleep onset, sleep maintenance, early morning awakening problems; sleep dissatisfaction; interference of sleep problem with daytime functioning; noticeability of sleep problems by others; distress caused by sleep difficulties. 5-point Likert scale (0-4) is used to rate each item, total score ranging from 0-28 and interpreted as follows: absence of insomnia (0-7); sub-threshold insomnia (8-14); moderate insomnia (15-21); severe insomnia (22-28). FAS included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. Here, N (number of subjects analyzed) signifies number of subjects evaluable for this endpoint. Subjects with missing values at a given time point are excluded from the frequency calculation for that time point.

End point type	Secondary

End point timeframe:

Day 14

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	69	69	73	69
Units: Percentage of Subjects				
number (not applicable)	24.6	43.5	37.0	39.1

End point values	Zolpidem			
Subject group type	Reporting group			
Number of subjects analysed	70			
Units: Percentage of Subjects				
number (not applicable)	50.0			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Clinician's Assessment of Insomnia Severity Using the Clinical Global Impression - Severity (CGI-S) Total Score on Day 14

End point title	Change from Baseline in Clinician's Assessment of Insomnia Severity Using the Clinical Global Impression - Severity (CGI-S) Total Score on Day 14

End point description:

The CGI-S is a 7-point scale to measure severity of illness (1=normal [not at all ill], 2=borderline ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severely ill, 7=among the most extremely ill patients). Higher score indicates more severity. Negative changes in scores indicate improvement. FAS included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. Here, N (number of subjects analyzed) signifies number of subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline and Day 14

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	69	69	73	69
Units: Units on a scale				
median (full range (min-max))				
Compared with Placebo	0.0 (-5 to 1)	-1.0 (-5 to 3)	-1.0 (-5 to 2)	-1.0 (-5 to 1)
Compared with Zolpidem	0.0 (-5 to 1)	-1.0 (-5 to 3)	-1.0 (-5 to 2)	-1.0 (-5 to 1)

End point values	Zolpidem			
Subject group type	Reporting group			
Number of subjects analysed	70			
Units: Units on a scale				
median (full range (min-max))				
Compared with Placebo	-1.0 (-5 to 0)			
Compared with Zolpidem	-1.0 (-5 to 0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in in Clinician's Assessment of Insomnia Improvement Using Clinical Global Impression-Improvement (CGI-I) Total Score on Day 14

End point title	Change from Baseline in in Clinician's Assessment of Insomnia Improvement Using Clinical Global Impression-Improvement (CGI-I) Total Score on Day 14

End point description:

The CGI-I is a 7-point scale to measure improvement in illness (1=very much improved, 2=much

improved, 3=minimally improved, 4=no change from baseline, 5=minimally worse, 6=much worse, 7=very much worse). Higher score indicates more severity. Negative changes in scores indicate improvement. FAS included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. Here, N (number of subjects analyzed) signifies number of subjects evaluable for this endpoint.

End point type	Secondary
End point timeframe:	
Baseline and Day 14	

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	69	69	73	69
Units: Units on a Scale				
median (full range (min-max))				
Compared with Placebo	3.0 (1 to 5)	3.0 (1 to 5)	3.0 (1 to 4)	3.0 (1 to 5)
Compared with Zolpidem	3.0 (1 to 5)	3.0 (1 to 5)	3.0 (1 to 4)	3.0 (1 to 5)

End point values	Zolpidem			
Subject group type	Reporting group			
Number of subjects analysed	70			
Units: Units on a Scale				
median (full range (min-max))				
Compared with Placebo	2.0 (1 to 5)			
Compared with Zolpidem	2.0 (1 to 5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Treatment-Emergent Adverse Events (TEAEs) as a Measure of Safety and Tolerability

End point title	Number of Subjects with Treatment-Emergent Adverse Events (TEAEs) as a Measure of Safety and Tolerability

End point description:

An adverse event is any untoward medical event that occurs in a participant administered an investigational product, and it does not necessarily indicate only events with clear causal relationship with the relevant investigational product. TEAE defined as the number of subjects who experience at least 1 occurrence of the given event summarized by system organ class, preferred term, and treatment group. Safety analysis set (SAS) included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. One subject who was randomized to JNJ-42847922 10 mg dose group received 5 mg of JNJ-42847922. This subject was summarized under the 5 mg dose group for safety analyses.

End point type	Secondary
End point timeframe:	
Up to Day 17	

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	75	72	73	71
Units: Subjects	37	29	23	21

End point values	Zolpidem			
Subject group type	Subject analysis set			
Number of subjects analysed	73			
Units: Subjects	31			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Treatment-Emergent Serious Adverse Events and Events of Special Interest

End point title	Number of Subjects with Treatment-Emergent Serious Adverse Events and Events of Special Interest

End point description:

TEAE is any untoward medical occurrence that at any dose results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly, is a suspected transmission of any infectious agent via a medicinal product and events of special interest include: Cataplexy; Sleep paralysis; Complex sleep-related behaviors such as confusional arousals, somnambulism (sleep walking), sleep terrors, bruxism (teeth grinding), sleep sex, sleep related eating disorder, sleep behavior disorder, and catathrenia (REM-associated end-inspiratory apnea/breath holding); Abnormal dreams; Falls. SAS included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. One subject who was randomized to JNJ-42847922 10 mg dose group received 5 mg of JNJ-42847922. This subject was summarized under the 5 mg dose group for safety analyses.

End point type	Secondary

End point timeframe:

Up to Day 17

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	75	72	73	71
Units: Subjects				
Treatment-emergent Serious AE	0	0	0	1
Events of Special Interest	2	1	2	1

End point values	Zolpidem			
Subject group type	Subject analysis set			
Number of subjects analysed	73			
Units: Subjects				
Treatment-emergent Serious AE	1			
Events of Special Interest	4			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Clinically Significant Vital Signs and Physical Abnormalities

End point title	Number of Subjects With Clinically Significant Vital Signs and Physical Abnormalities

End point description:

Abnormally low parameters include pulse (bpm)- Decrease value from baseline greater than or equal to (>=) 15 to <=50; Systolic BP (mmHg [Millimetre of mercury])- Decrease value from baseline >=20 to <=90; Diastolic BP- decrease value from baseline >=15 to <=50; weight (Kilogram[Kg])- Decrease from baseline >=7%; Body temperature (Celsius [C])- <35.5; Abnormally high parameters include pulse- increase value from baseline >=15 to >=100; Systolic BP(mmHg)- Increase from baseline of >=20 to >=180; Diastolic BP- increase value from baseline>=15 to >=105; weight(Kg)- increase from baseline of >=7%; body temperature (C)- >37.5. SAS included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. One subject who was randomized to JNJ-42847922 10 mg dose group received 5 mg of JNJ-42847922. This subject was summarized under the 5 mg dose group for safety analyses.

End point type	Secondary

End point timeframe:

Up to Day 15

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	75	72	73	71
Units: Subjects				
Supine Pulse Rate: Abnormally low	2	2	2	3
Supine Pulse Rate: Abnormally high	1	0	0	0
Standing Pulse Rate: Abnormally low	1	0	0	1
Standing Pulse Rate: Abnormally high	8	7	3	6
Supine Systolic BP: Abnormally low	3	0	3	2
Supine Systolic BP: Abnormally high	1	0	0	0
Standing Systolic BP: Abnormally low	2	1	1	3
Standing Systolic BP: Abnormally high	2	0	0	0
Supine Diastolic BP: Abnormally low	2	0	0	0
Supine Diastolic BP: Abnormally high	0	1	0	0
Standing Diastolic BP: Abnormally low	0	1	0	1

Standing Diastolic BP: Abnormally high	0	0	0	0
Temperature: Abnormally low	2	3	0	3
Temperature: Abnormally high	1	0	0	2
Weight: Abnormally low	0	0	0	1
Weight: Abnormally high	2	0	0	0

End point values	Zolpidem			
Subject group type	Subject analysis set			
Number of subjects analysed	73			
Units: Subjects				
Supine Pulse Rate: Abnormally low	0			
Supine Pulse Rate: Abnormally high	1			
Standing Pulse Rate: Abnormally low	1			
Standing Pulse Rate: Abnormally high	11			
Supine Systolic BP: Abnormally low	2			
Supine Systolic BP: Abnormally high	0			
Standing Systolic BP: Abnormally low	5			
Standing Systolic BP: Abnormally high	0			
Supine Diastolic BP: Abnormally low	4			
Supine Diastolic BP: Abnormally high	1			
Standing Diastolic BP: Abnormally low	0			
Standing Diastolic BP: Abnormally high	1			
Temperature: Abnormally low	2			
Temperature: Abnormally high	1			
Weight: Abnormally low	0			
Weight: Abnormally high	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Clinically Significant Electrocardiogram (ECG) Abnormalities

End point title	Number of Subjects With Clinically Significant Electrocardiogram (ECG) Abnormalities

End point description:

Twelve-lead ECGs was recorded in a supine position and different ECG intervals (RR, PR, QRS, and QT) and heart rate was measured. SAS included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. Here, N (number of subjects analyzed) signifies number of subjects evaluable for this endpoint. Here, 'n' (number analyzed) signifies number of subjects who were evaluable at specified time points. Here, bpm indicates beats per minute. One subject who was randomized to JNJ-42847922 10 mg dose group received 5 mg of JNJ-42847922. This subject was summarized under the 5 mg dose group for safety analyses.

End point type	Secondary

End point timeframe:

Up to Day 14

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	74	69	73	68
Units: Subjects				
Heart rate: <=50 bpm (n=74, 70, 71, 68, 71)	10	7	5	6
Heart rate:>=100 bpm (n=74, 70, 71, 68, 71)	0	0	0	0
PR interval: <=120 msec (n=74, 69, 71, 68, 71)	0	0	0	1
PR interval: >=200 msec (n=74, 70, 71, 68, 71)	4	4	4	2
QRS interval: <=60 msec (n=74, 70, 71, 68, 71)	0	0	0	0
QRS interval: >=120 msec (n=74, 70, 71, 68, 71)	0	0	0	0
QT interval: <=200 msec (n=74, 70, 71, 68, 71)	0	0	0	0
QT interval: >=500 msec (n=74, 70, 71, 68, 71)	1	0	0	1

End point values	Zolpidem			
Subject group type	Subject analysis set			
Number of subjects analysed	71			
Units: Subjects				
Heart rate: <=50 bpm (n=74, 70, 71, 68, 71)	6			
Heart rate:>=100 bpm (n=74, 70, 71, 68, 71)	0			
PR interval: <=120 msec (n=74, 69, 71, 68, 71)	0			
PR interval: >=200 msec (n=74, 70, 71, 68, 71)	7			
QRS interval: <=60 msec (n=74, 70, 71, 68, 71)	0			
QRS interval: >=120 msec (n=74, 70, 71, 68, 71)	0			
QT interval: <=200 msec (n=74, 70, 71, 68, 71)	0			
QT interval: >=500 msec (n=74, 70, 71, 68, 71)	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Clinically Significant Laboratory Abnormalities

End point title	Number of Subjects With Clinically Significant Laboratory Abnormalities

End point description:

Number of subjects with clinically significant laboratory abnormalities was assessed. Blood samples for serum chemistry (albumin, alkaline phosphatase etc), hematology (hemoglobin, hematocrit, etc), and urinalysis (pH, specific gravity, etc) was collected for clinical laboratory testing. SAS included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. Here, N (number of subjects analyzed) signifies number of subjects evaluable for this endpoint. Here, 'n' (number analyzed) signifies number of subjects who were evaluable at specified time points. One subject who was randomized to JNJ-42847922 10 mg dose group received 5 mg of JNJ-42847922. This subject was summarized under the 5 mg dose group for safety analyses. Here, Abn., ALT , AST, GGT signifies abnormally, Alanine Aminotransferase, Aspartate Aminotransferase, Gamma Glutamyl Transferase respectively.

End point type	Secondary

End point timeframe:

Up to Day 15

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	69	72	73	68
Units: Subjects				
ALT: Abnormally high(n=69, 70, 69, 67, 71)	0	0	0	0
Albumin: Abnormally low (n=69, 70, 71, 68, 71)	0	0	0	0
Albumin: Abnormally high (n=69, 70, 71, 68, 71)	0	0	0	0
Alkaline Phosphatase: Abn. high(n=69,70,70,68,71)	0	0	0	0
AST: Abnormally high (n=69, 70, 69, 67, 71)	0	0	0	0
Bicarbonate: Abnormally low (n=69, 70, 69, 67, 71)	0	0	0	0
Bicarbonate: Abn. high (n=69, 70, 69, 67, 71)	0	0	0	0
Bilirubin: Abnormally high (n=69, 70, 69, 67, 71)	0	0	0	0
Calcium: Abnormally low (n=69, 70, 70, 68, 71)	0	0	0	0
Calcium: Abnormally high (n=69, 70, 70, 68, 71)	0	0	0	0
Chloride: Abnormally low (n=69, 70, 70, 68, 71)	1	0	0	0
Chloride: Abnormally high (n=69, 70, 70, 68, 71)	0	0	0	0
Creatine Kinase: Abn. high (n=69, 70, 69, 67, 71)	0	0	0	0
Creatinine: Abnormally high (n=69, 70, 70, 68, 71)	0	1	0	0
Direct Bilirubin: Abn. high (n=68, 70, 69, 66, 70)	0	0	0	0
GGT: Abnormally high (n=69, 70, 70, 68, 71)	0	0	0	0
Lactate Dehydrogenase: Abn. high(n=62,68,65,65,64)	0	0	1	0
Phosphate: Abnormally low (n=69, 70, 71, 68, 71)	0	0	0	0

Phosphate: Abnormally high (n=69, 70, 71, 68, 71)	0	0	0	0
Potassium: Abnormally low (n=69, 70, 70, 68, 71)	0	0	0	0
Potassium: Abnormally high(n=69, 70, 70, 68, 71)	0	0	3	1
Protein: Abnormally low (n=69, 70, 70, 68, 71)	0	1	0	0
Sodium: Abnormally low (n=69, 70, 70, 68, 71)	0	0	0	0
Sodium: Abnormally high (n=69, 70, 70, 68, 71)	0	0	0	0

End point values	Zolpidem			
Subject group type	Subject analysis set			
Number of subjects analysed	71			
Units: Subjects				
ALT: Abnormally high(n=69, 70, 69, 67, 71)	0			
Albumin: Abnormally low (n=69, 70, 71, 68, 71)	0			
Albumin: Abnormally high (n=69, 70, 71, 68, 71)	0			
Alkaline Phosphatase: Abn. high(n=69,70,70,68,71)	0			
AST: Abnormally high (n=69, 70, 69, 67, 71)	0			
Bicarbonate: Abnormally low (n=69, 70, 69, 67, 71)	0			
Bicarbonate: Abn. high (n=69, 70, 69, 67, 71)	0			
Bilirubin: Abnormally high (n=69, 70, 69, 67, 71)	0			
Calcium: Abnormally low (n=69, 70, 70, 68, 71)	0			
Calcium: Abnormally high (n=69, 70, 70, 68, 71)	0			
Chloride: Abnormally low (n=69, 70, 70, 68, 71)	0			
Chloride: Abnormally high (n=69, 70, 70, 68, 71)	0			
Creatine Kinase: Abn. high (n=69, 70, 69, 67, 71)	0			
Creatinine: Abnormally high (n=69, 70, 70, 68, 71)	0			
Direct Bilirubin: Abn. high (n=68, 70, 69, 66, 70)	0			
GGT: Abnormally high (n=69, 70, 70, 68, 71)	0			
Lactate Dehydrogenase: Abn. high(n=62,68,65,65,64)	0			
Phosphate: Abnormally low (n=69, 70, 71, 68, 71)	0			
Phosphate: Abnormally high (n=69, 70, 71, 68, 71)	0			
Potassium: Abnormally low (n=69, 70, 70, 68, 71)	0			

Potassium: Abnormally high(n=69, 70, 70, 68, 71)	2				
Protein: Abnormally low (n=69, 70, 70, 68, 71)	0				
Sodium: Abnormally low (n=69, 70, 70, 68, 71)	0				
Sodium: Abnormally high (n=69, 70, 70, 68, 71)	0				

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Suicidal Ideation as Determined by Columbia Suicide Severity Rating Scale (C-SSRS) Total Score

End point title	Number of Subjects with Suicidal Ideation as Determined by Columbia Suicide Severity Rating Scale (C-SSRS) Total Score

End point description:

C-SSRS is a questionnaire designed to solicit occurrence, severity, frequency of suicidal ideation/behaviors using following scores: Suicidal Ideation (1:Wish to be Dead; 2:Non-specific Active Suicidal Thoughts; 3:Active Suicidal Ideation with Any Methods without Intent to Act; 4:Active Suicidal Ideation with Some Intent to Act; 5:Active Suicidal Ideation with Specific Plan/Intent). Suicidal Behavior (6:Preparatory Acts; 7:Aborted Attempt; 8:Interrupted Attempt; 9:Actual Attempt; 10:Completed Suicide). If no events qualify for score of 1-10, score 0 indicate "no event that can be assessed on basis of C-SSRS". Higher scores= greater severity. SAS included all subjects who were randomly assigned to drug and received at least 1 dose of drug. Here, N (number of subjects analyzed) signifies number of subjects evaluable for this endpoint. 1 subject who was randomized to JNJ-42847922 10 mg dose group received 5 mg of JNJ-42847922 and was summarized under 5 mg dose group for safety analyses.

End point type	Secondary

End point timeframe:

Day 14

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	69	72	73	69
Units: Subjects				
Score 0: No Event	69	72	73	69
Score 1: Wish to be Dead	0	0	0	0
Score 2: Non-Specific Active Suicidal Thoughts	0	0	0	0
Score 3: Suic Ideation Without Plan and Intent	0	0	0	0
Score 4: Suic Ideation Intent to Act Without Plan	0	0	0	0
Score 5: Suic Ideation With Plan and Intent	0	0	0	0
Score 6: Preparatory Acts or Behavior	0	0	0	0
Score 7: Aborted Attempt	0	0	0	0
Score 8: Interrupted Attempt	0	0	0	0
Score 9: Actual Attempt	0	0	0	0
Score 10: Completed Suicide	0	0	0	0

End point values	Zolpidem			
Subject group type	Subject analysis set			
Number of subjects analysed	70			
Units: Subjects				
Score 0: No Event	70			
Score 1: Wish to be Dead	0			
Score 2: Non-Specific Active Suicidal Thoughts	0			
Score 3: Suic Ideation Without Plan and Intent	0			
Score 4: Suic Ideation Intent to Act Without Plan	0			
Score 5: Suic Ideation With Plan and Intent	0			
Score 6: Preparatory Acts or Behavior	0			
Score 7: Aborted Attempt	0			
Score 8: Interrupted Attempt	0			
Score 9: Actual Attempt	0			
Score 10: Completed Suicide	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Karolinska Sleepiness Scale (KSS) Total Score on Days 2 and 14

End point title	Change from Baseline in Karolinska Sleepiness Scale (KSS) Total Score on Days 2 and 14

End point description:

The KSS is a patient reported assessment of level of drowsiness at the time of scale administration. This scale is focused mainly on the propensity to fall asleep and has a high validity in measuring sleepiness. It consists of a 9-point Likert scale with response options from: 1=very alert, 3=alert, 5=neither alert nor sleepy, 7=sleepy (but not fighting sleep), 9=very sleepy (fighting sleep). SAS included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. Here, N (number of subjects analyzed) signifies number of subjects evaluable for this endpoint. Here, 'n' (number analyzed) signifies number of subjects who were evaluable at specified time points. One subject who was randomized to JNJ-42847922 10 mg dose group received 5 mg of JNJ-42847922. This subject was summarized under the 5 mg dose group for safety analyses.

End point type	Secondary

End point timeframe:

Baseline, Days 2 and 14

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	66	62	65	59
Units: Units on a Scale				
arithmetic mean (standard deviation)				
Day 2 (n=66, 61, 65, 59, 67)	0.3 (± 1.75)	-0.4 (± 1.86)	-0.2 (± 1.42)	-0.5 (± 1.86)
Day 14 (n=63, 62, 62, 59, 65)	0.1 (± 1.82)	-0.8 (± 2.15)	-0.6 (± 1.72)	-0.7 (± 1.90)

End point values	Zolpidem			
Subject group type	Subject analysis set			
Number of subjects analysed	67			
Units: Units on a Scale				
arithmetic mean (standard deviation)				
Day 2 (n=66, 61, 65, 59, 67)	-0.4 (± 1.68)			
Day 14 (n=63, 62, 62, 59, 65)	-0.7 (± 2.01)			

Statistical analyses

No statistical analyses for this end point

Secondary: Next-Day Residual Effects Measured by Postural Stability (Body Sway)

End point title	Next-Day Residual Effects Measured by Postural Stability (Body Sway)

End point description:

The body sway meter allows measurement of body movements in a single plane, providing a measure of postural stability. Body sway is measured using an ataxiameter. Subjects were instructed to wear a pair of thin socks for each session. Before starting a measurement, subjects were asked to stand still and comfortable, with their feet approximately 10 centimeters (cm) apart and their hands in a relaxed position alongside the body and eyes closed. The total period of body sway measurement was 2 minutes. SAS included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. Here, N (number of subjects analyzed) signifies number of subjects evaluable for this endpoint. Here, 'n' (number analyzed) signifies number of subjects who were evaluable at specified time points. One subject who was randomized to JNJ-42847922 10 mg dose group received 5 mg of JNJ-42847922. This subject was summarized under the 5 mg dose group for safety analyses.

End point type	Secondary

End point timeframe:

Day 14 (morning)

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	66	66	69	67
Units: 1/3 Degree Angle of Arc				
arithmetic mean (standard deviation)	-0.06 (± 17.15)	3.14 (± 16.14)	-0.87 (± 15.62)	-0.25 (± 14.71)

End point values	Zolpidem			
Subject group type	Subject analysis set			
Number of subjects analysed	69			
Units: 1/3 Degree Angle of Arc				
arithmetic mean (standard deviation)	1.65 (± 14.11)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Power of Attention as Measured by a Computerized Battery of Cognitive Tests on Day 14 (Morning)

End point title	Change From Baseline in Power of Attention as Measured by a Computerized Battery of Cognitive Tests on Day 14 (Morning)

End point description:

Power of Attention is a combination of the speed scores from the three tests of attention, and is established to reflect the ability to focus attention and to process information. Larger scores reflect poorer ability. The sum of the reaction time measures from the attentional tasks (Simple Reaction Time, Choice Reaction Time and Digit Vigilance Speed). SAS included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. Here, N (number of subjects analyzed) signifies number of subjects evaluable for this endpoint. One subject who was randomized to JNJ-42847922 10 mg dose group received 5 mg of JNJ-42847922. This subject was summarized under the 5 mg dose group for safety analyses.

End point type	Secondary

End point timeframe:

Baseline and Day 14 (Morning)

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	67	66	68	67
Units: millisecond (ms)				
arithmetic mean (standard deviation)	35.88 (± 125.43)	48.59 (± 137.75)	67.09 (± 257.67)	37.07 (± 124.23)

End point values	Zolpidem			
Subject group type	Subject analysis set			
Number of subjects analysed	69			
Units: millisecond (ms)				
arithmetic mean (standard deviation)	35.38 (± 189.99)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Continuity of Attention as Measured by a Computerized Battery of Cognitive Tests on Day 14 (Morning)

End point title	Change From Baseline in Continuity of Attention as Measured by a Computerized Battery of Cognitive Tests on Day 14 (Morning)

End point description:

Continuity of Attention is a combination of the speed scores from the Choice Reaction Time and Digit Vigilance tasks and reflects the ability to sustain attention over time. Smaller scores indicate poorer ability. The sum of the accuracy measures from the attentional tasks (Choice Reaction Time and Digit Vigilance Accuracy) minus Digit Vigilance False Alarms (errors). SAS included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. Here, N (number of subjects analyzed) signifies number of subjects evaluable for this endpoint. One subject who was randomized to JNJ-42847922 10 mg dose group received 5 mg of JNJ-42847922. This subject was summarized under the 5 mg dose group for safety analyses.

End point type	Secondary

End point timeframe:

Baseline and Day 14 (Morning)

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	67	66	68	67
Units: Number				
arithmetic mean (standard deviation)	0.36 (± 5.31)	-0.20 (± 3.16)	-1.37 (± 6.35)	0.10 (± 5.05)

End point values	Zolpidem			
Subject group type	Subject analysis set			
Number of subjects analysed	69			
Units: Number				
arithmetic mean (standard deviation)	-0.39 (± 5.14)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Quality of Working Memory as Measured by a

Computerized Battery of Cognitive Tests on Day 14 (Morning)

End point title	Change From Baseline in Quality of Working Memory as Measured by a Computerized Battery of Cognitive Tests on Day 14 (Morning)

End point description:

Quality of working memory is a combination of the scores from Spatial Working Memory and Numeric Working Memory tasks, and is established to reflect the ability to temporarily hold numeric and spatial information in memory. Smaller scores reflect poorer ability. The sum of Spatial and Numeric Working Memory sensitivity indices (accuracy). SAS included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. Here, N (number of subjects analyzed) signifies number of subjects evaluable for this endpoint. One subject who was randomized to JNJ-42847922 10 mg dose group received 5 mg of JNJ-42847922. This subject was summarized under the 5 mg dose group for safety analyses.

End point type	Secondary

End point timeframe:

Baseline and Day 14 (Morning)

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	67	65	68	67
Units: Number				
arithmetic mean (standard deviation)	0.00 (± 0.35)	-0.03 (± 0.28)	-0.02 (± 0.41)	-0.04 (± 0.29)

End point values	Zolpidem			
Subject group type	Subject analysis set			
Number of subjects analysed	69			
Units: Number				
arithmetic mean (standard deviation)	-0.05 (± 0.28)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Quality of Episodic Secondary Memory as Measured by a Computerized Battery of Cognitive Tests on Day 14 (Morning)

End point title	Change From Baseline in Quality of Episodic Secondary Memory as Measured by a Computerized Battery of Cognitive Tests on Day 14 (Morning)

End point description:

Quality of Episodic Secondary Memory is a combination of accuracy measures from Word Recognition, Immediate Word Recall and Delayed Word Recall tasks and reflects the ability to store and retrieve information in episodic memory. Smaller scores reflect poorer ability. The sum of accuracy measures from the Immediate and Delayed Word Recall tasks, adjusted for errors, and from the word and picture recognition tasks. SAS included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. Here, N (number of subjects analyzed) signifies number of subjects evaluable for this endpoint. One subject who was randomized to JNJ-42847922 10 mg dose group received 5 mg of JNJ-42847922. This subject is summarized under the 5 mg dose group.

End point type	Secondary

End point timeframe:

Baseline and Day 14 (Morning)

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	66	65	68	66
Units: Number				
arithmetic mean (standard deviation)	-22.84 (± 53.73)	-23.15 (± 46.02)	-33.58 (± 48.82)	-25.45 (± 56.37)

End point values	Zolpidem			
Subject group type	Subject analysis set			
Number of subjects analysed	67			
Units: Number				
arithmetic mean (standard deviation)	-37.96 (± 55.94)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Speed of Memory as Measured by a Computerized Battery of Cognitive Tests on Day 14 (Morning)

End point title	Change From Baseline in Speed of Memory as Measured by a Computerized Battery of Cognitive Tests on Day 14 (Morning)

End point description:

The sum of the speed measures from the two working memory tasks (Spatial and Numeric) and the two recognition tasks (Word and Picture). Speed of Memory combines reaction times from Spatial Working Memory, Numeric Working Memory, Word Recognition and Picture recognition tasks. This score measures memory retrieval speed. Larger scores reflect poorer ability. SAS included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. Here, N (number of subjects analyzed) signifies number of subjects evaluable for this endpoint. One subject who was randomized to JNJ-42847922 10 mg dose group received 5 mg of JNJ-42847922. This subject was summarized under the 5 mg dose group for safety analyses.

End point type	Secondary

End point timeframe:

Baseline and Day 14 (Morning)

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	67	65	68	67
Units: millisecond				
arithmetic mean (standard deviation)	-104.75 (± 787.74)	258.38 (± 719.56)	7.57 (± 806.27)	-65.67 (± 761.77)

End point values	Zolpidem			
Subject group type	Subject analysis set			
Number of subjects analysed	69			
Units: millisecond				
arithmetic mean (standard deviation)	-83.70 (± 1060.38)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Subjective Sleep Parameters From Day 14 as Compared to Day 17 as Measured by the Consensus Sleep Diary–Morning Administration (CSD-M):Self-Reported Sleep-Onset Latency (sSOL), Subjective Wake After Sleep Onset (sWASO), sTST

End point title	Change in Subjective Sleep Parameters From Day 14 as Compared to Day 17 as Measured by the Consensus Sleep Diary–Morning Administration (CSD-M):Self-Reported Sleep-Onset Latency (sSOL), Subjective Wake After Sleep Onset (sWASO), sTST

End point description:

CSD-M is a standardized subject diary based on expert consensus and qualitative subject input to retrieve patient reported subjective sleep parameters related to prior night's sleep. It allows for calculation of total time spent in bed and SE as percentage of time asleep out of amount of time spent in bed. Sleep quality and how well rested subjects felt at awaking are rated on a 5-point Likert scale ranging from 0 (very poor) to 4 (very good). Higher ratings indicate better sleep quality and more refreshing/restorative quality of sleep. Negative change in sSOL, sWASO indicate improvement and positive change in Subjective Total Sleep Time (sTST) indicates improvement. FAS included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. Here, N (number of subjects analyzed) signifies number of subjects evaluable for this endpoint. Here, 'n' (number analyzed) signifies number of subjects who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

Day 14 to Day 17

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	63	58	67	56
Units: Minutes				
arithmetic mean (standard deviation)				
sSOL (n=63, 58, 57,56,58)	-20.56 (± 74.145)	-4.83 (± 43.769)	9.67 (± 29.798)	15.55 (± 32.327)
sWASO (n=57, 51, 52,51,51)	-12.39 (± 57.711)	-0.76 (± 66.663)	-2.13 (± 41.505)	-10.80 (± 63.672)
sTST (n=63, 58, 57, 56, 58)	30.95 (± 101.367)	13.07 (± 102.093)	6.96 (± 96.664)	19.71 (± 66.447)

End point values	Zolpidem			
Subject group type	Reporting group			
Number of subjects analysed	58			
Units: Minutes				
arithmetic mean (standard deviation)				
sSOL (n=63, 58, 57,56,58)	9.57 (± 72.253)			
sWASO (n=57, 51, 52,51,51)	3.76 (± 58.805)			
sTST (n=63, 58, 57, 56, 58)	-7.95 (± 102.183)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Subjective Sleep Parameters From Day 14 as Compared to Day 17 Using Consensus Sleep Diary–Morning Administration: Subjective Refreshed Feeling on Waking (sFRESH) and Subjective Quality of Sleep (sQUAL)

End point title	Change in Subjective Sleep Parameters From Day 14 as Compared to Day 17 Using Consensus Sleep Diary–Morning Administration: Subjective Refreshed Feeling on Waking (sFRESH) and Subjective Quality of Sleep (sQUAL)

End point description:

CSD-M is a standardized subject diary based on expert consensus and qualitative subject input to retrieve patient reported subjective sleep parameters related to the prior night's sleep. It allows for calculation of total time spent in bed and SE as the percentage of time asleep out of amount of time spent in bed. Sleep quality and how well rested subjects felt at awaking are rated on a 5-point Likert scale ranging from 1 (very poor) to 5 (very good). Higher ratings indicate better sleep quality and more refreshing/restorative quality of sleep. CSD-M parameters analyzed includes: sFRESH and sQUAL. Positive change in sFRESH and sQUAL indicates improvement. FAS included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. Here, N (number of subjects analyzed) signifies number of subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Day 14 to 17

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	63	58	57	56
Units: Units on a Scale				
arithmetic mean (standard deviation)				
sFRESH	0.13 (± 1.085)	0.17 (± 1.011)	0.04 (± 1.017)	0.11 (± 1.073)
sQUAL	0.19 (± 1.242)	0.24 (± 1.129)	-0.07 (± 1.083)	0.02 (± 1.120)

End point values	Zolpidem			
Subject group type	Reporting group			
Number of subjects analysed	58			
Units: Units on a Scale				
arithmetic mean (standard deviation)				
sFRESH	-0.03 (± 0.898)			
sQUAL	-0.12 (± 1.010)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Subjective Sleep Parameters From Day 14 as Compared to Day 17 Using Consensus Sleep Diary–Morning Administration (CSD-M): Number of Nighttime Awakenings (s-nNAW)

End point title	Change in Subjective Sleep Parameters From Day 14 as Compared to Day 17 Using Consensus Sleep Diary–Morning Administration (CSD-M): Number of Nighttime Awakenings (s-nNAW)

End point description:

CSD-M is a standardized subject diary based on expert consensus and qualitative subject input to retrieve patient reported subjective sleep parameters related to the prior night's sleep. It allows for calculation of total time spent in bed and SE (as the percentage of time asleep out of amount of time spent in bed). Sleep quality and how well rested subjects felt at awaking are rated on a 5-point Likert scale ranging from 1 (very poor) to 5 (very good). Higher ratings indicate better sleep quality and more refreshing/restorative quality of sleep. CSD-M parameters analyzed includes: s-nNAW. Negative change in s-nNAW indicate improvement. FAS included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. Here, N (number of subjects analyzed) signifies number of subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Day 14 to 17

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	63	58	57	56
Units: Number of awakening				
arithmetic mean (standard deviation)	0.16 (± 3.525)	-0.59 (± 2.009)	-0.35 (± 1.217)	-0.36 (± 1.052)

End point values	Zolpidem			
Subject group type	Reporting group			
Number of subjects analysed	58			
Units: Number of awakening				
arithmetic mean (standard deviation)	-0.34 (± 1.396)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects Withdrawal Symptoms of JNJ-42847922 as Measured by Physician Withdrawal Checklist (PWC) From Day 14 to Day 17

End point title	Number of Subjects Withdrawal Symptoms of JNJ-42847922 as Measured by Physician Withdrawal Checklist (PWC) From Day 14 to Day 17

End point description:

PWC-20 is a reliable, sensitive instrument used to assess potential withdrawal symptoms following cessation of treatment. Items are as follows: Loss of Appetite, Nausea-Vomiting, Diarrhea, Anxiety-Nervousness, Irritability, Dysphoric Mood-Depression, Insomnia, Fatigue, Poor Coordination, Restlessness, Diaphoresis, Tremor, Dizziness, Headaches, Stiffness, Weakness, Increased Acuity Sound Smell Touch (IASST), Paresthesias, Remember, Derealization. Each item score ranges from 0 (not present)-3 (severe), where higher scores = more affected condition. Total score ranges from 0-60 where higher score indicates more affected condition. SAS included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. Here, N (number of subjects analyzed) signifies number of subjects evaluable for this endpoint. 1 subject who was randomized to JNJ-42847922 10 mg dose group received 5 mg of JNJ-42847922 and was summarized under 5 mg dose group for safety analyses.

End point type	Secondary

End point timeframe:

Day 14 to 17

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	69	69	70	68
Units: Subjects				
Loss of Appetite: No Symptoms	65	69	65	68
Loss of Appetite: Improved Symptoms	0	0	4	0
Loss of Appetite: Symptoms Present and Unchanged	0	0	0	0
Loss of Appetite: New or Worsened Symptoms	4	0	1	0
Nausea-Vomiting: No Symptoms	67	67	66	67
Nausea-Vomiting: Improved Symptoms	0	1	3	0
Nausea-Vomiting: Symptoms Present and Unchanged	0	0	0	0
Nausea-Vomiting: New or Worsened Symptoms	2	1	1	1
Diarrhea: No Symptoms	65	69	67	67
Diarrhea: Improved Symptoms	2	0	1	1
Diarrhea: Symptoms Present and Unchanged	0	0	1	0
Diarrhea: New or Worsened Symptoms	2	0	1	0
Anxiety-Nervousness: No Symptoms	64	68	64	62
Anxiety-Nervousness:Improved Symptoms	2	1	3	3
Anxiety-Nervousness:Symptoms Present and Unchanged	2	0	1	2
Anxiety-Nervousness: New or Worsened Symptoms	1	0	2	1
Irritability: No Symptoms	58	58	59	60
Irritability:Improved Symptoms	6	9	5	4
Irritability:Symptoms Present and Unchanged	3	1	3	3
Irritability:New or Worsened Symptoms	2	1	3	1
Dysphoric Mood: No Symptoms	66	66	68	65
Dysphoric Mood: Improved Symptoms	0	3	1	1
Dysphoric Mood: Symptoms Present and Unchanged	2	0	1	1
Dysphoric Mood: New or Worsened Symptoms	1	0	0	1
Insomnia: No Symptoms	12	14	11	17
Insomnia: Improved Symptoms	19	15	13	11
Insomnia: Symptoms Present and Unchanged	27	28	32	28
Insomnia: New or Worsened Symptoms	11	12	14	12
Fatigue: No Symptoms	30	43	41	45
Fatigue: Improved Symptoms	21	15	19	8
Fatigue: Symptoms Present and Unchanged	5	7	8	9
Fatigue: New or Worsened Symptoms	13	4	2	6
Poor Coordination: No Symptoms	61	65	63	61
Poor Coordination: Improved Symptoms	6	3	7	5
Poor Coordination: Symptoms Present and Unchanged	1	1	0	1
Poor Coordination: New/Worsened Symptoms	1	0	0	1
Restlessness:No Symptoms	55	59	59	60

Restlessness:Improved Symptoms	9	6	9	5
Restlessness:Symptoms Present and Unchanged	3	2	1	1
Restlessness:New or Worsened Symptoms	2	2	1	2
Diaphoresis:No Symptoms	64	68	65	65
Diaphoresis:Improved Symptoms	3	1	2	2
Diaphoresis:Symptoms Present and Unchanged	0	0	0	0
Diaphoresis:New or Worsened Symptoms	2	0	3	1
Tremor: No Symptoms	66	68	69	68
Tremor: Improved Symptoms	2	0	0	0
Tremor: Symptoms Present and Unchanged	0	1	0	0
Tremor: New or Worsened Symptoms	1	0	1	0
Dizziness:No Symptoms	63	69	66	64
Dizziness: Improved Symptoms	3	0	2	3
Dizziness: Symptoms Present and Unchanged	1	0	1	1
Dizziness:New or Worsened Symptoms	2	0	4	0
Headaches:No Symptoms	56	51	61	60
Headaches:Improved Symptoms	9	12	2	7
Headaches:Symptoms Present and Unchanged	2	5	3	0
Headaches:New or Worsened Symptoms	2	1	2	1
Stiffness:No Symptoms	59	62	64	63
Stiffness:Improved Symptoms	8	2	2	3
Stiffness:Symptoms Present and Unchanged	1	2	2	0
Stiffness:New or Worsened Symptoms	1	3	2	2
Weakness:No Symptoms	61	69	65	65
Weakness:Improved Symptoms	3	0	3	3
Weakness:Symptoms Present and Unchanged	3	0	1	0
Weakness:New or Worsened Symptoms	2	0	1	0
IASST: No Symptoms	64	66	66	63
IASST: Improved Symptoms	1	1	1	3
IASST: Symptoms Present and Unchanged	2	1	0	0
IASST: New or Worsened Symptoms	2	1	3	2
Paresthesias:No Symptoms	62	68	66	68
Paresthesias:Improved Symptoms	4	0	2	0
Paresthesias:Symptoms Present and Unchanged	1	1	0	0
Paresthesias:New or Worsened Symptoms	2	0	2	0
Remember:No Symptoms	50	60	56	56
Remember:Improved Symptoms	9	7	1	8
Remember:Symptoms Present and Unchanged	5	1	4	1
Remember:New or Worsened Symptoms	5	1	1	3
Derealization:No Symptoms	64	68	68	67
Derealization:Improved Symptoms	4	1	1	1
Derealization:Symptoms Present and Unchanged	0	0	0	0

Derealization:New or Worsened Symptoms	1	0	1	0

End point values	Zolpidem			
Subject group type	Subject analysis set			
Number of subjects analysed	69			
Units: Subjects				
Loss of Appetite: No Symptoms	66			
Loss of Appetite: Improved Symptoms	1			
Loss of Appetite: Symptoms Present and Unchanged	0			
Loss of Appetite: New or Worsened Symptoms	2			
Nausea-Vomiting: No Symptoms	63			
Nausea-Vomiting: Improved Symptoms	5			
Nausea-Vomiting: Symptoms Present and Unchanged	1			
Nausea-Vomiting: New or Worsened Symptoms	0			
Diarrhea: No Symptoms	63			
Diarrhea: Improved Symptoms	4			
Diarrhea: Symptoms Present and Unchanged	0			
Diarrhea: New or Worsened Symptoms	2			
Anxiety-Nervousness: No Symptoms	62			
Anxiety-Nervousness:Improved Symptoms	5			
Anxiety-Nervousness:Symptoms Present and Unchanged	0			
Anxiety-Nervousness: New or Worsened Symptoms	2			
Irritability: No Symptoms	58			
Irritability:Improved Symptoms	9			
Irritability:Symptoms Present and Unchanged	0			
Irritability:New or Worsened Symptoms	2			
Dysphoric Mood: No Symptoms	66			
Dysphoric Mood: Improved Symptoms	1			
Dysphoric Mood: Symptoms Present and Unchanged	0			
Dysphoric Mood: New or Worsened Symptoms	2			
Insomnia: No Symptoms	16			
Insomnia: Improved Symptoms	15			
Insomnia: Symptoms Present and Unchanged	21			
Insomnia: New or Worsened Symptoms	17			
Fatigue: No Symptoms	44			
Fatigue: Improved Symptoms	14			
Fatigue: Symptoms Present and Unchanged	5			
Fatigue: New or Worsened Symptoms	6			
Poor Coordination: No Symptoms	61			

Poor Coordination: Improved Symptoms	5				
Poor Coordination: Symptoms Present and Unchanged	1				
Poor Coordination: New/Worsened Symptoms	2				
Restlessness:No Symptoms	60				
Restlessness:Improved Symptoms	7				
Restlessness:Symptoms Present and Unchanged	1				
Restlessness:New or Worsened Symptoms	1				
Diaphoresis:No Symptoms	64				
Diaphoresis:Improved Symptoms	2				
Diaphoresis:Symptoms Present and Unchanged	1				
Diaphoresis:New or Worsened Symptoms	2				
Tremor: No Symptoms	67				
Tremor: Improved Symptoms	0				
Tremor: Symptoms Present and Unchanged	0				
Tremor: New or Worsened Symptoms	2				
Dizziness:No Symptoms	60				
Dizziness: Improved Symptoms	7				
Dizziness: Symptoms Present and Unchanged	1				
Dizziness:New or Worsened Symptoms	1				
Headaches:No Symptoms	56				
Headaches:Improved Symptoms	3				
Headaches:Symptoms Present and Unchanged	3				
Headaches:New or Worsened Symptoms	7				
Stiffness:No Symptoms	59				
Stiffness:Improved Symptoms	3				
Stiffness:Symptoms Present and Unchanged	1				
Stiffness:New or Worsened Symptoms	6				
Weakness:No Symptoms	65				
Weakness:Improved Symptoms	2				
Weakness:Symptoms Present and Unchanged	0				
Weakness:New or Worsened Symptoms	2				
IASST: No Symptoms	62				
IASST: Improved Symptoms	2				
IASST: Symptoms Present and Unchanged	1				
IASST: New or Worsened Symptoms	4				
Paresthesias:No Symptoms	68				
Paresthesias:Improved Symptoms	0				
Paresthesias:Symptoms Present and Unchanged	0				
Paresthesias:New or Worsened Symptoms	1				
Remember:No Symptoms	53				
Remember:Improved Symptoms	6				
Remember:Symptoms Present and Unchanged	5				

Remember:New or Worsened Symptoms	5
Derealization:No Symptoms	68
Derealization:Improved Symptoms	1
Derealization:Symptoms Present and Unchanged	0
Derealization:New or Worsened Symptoms	0

Statistical analyses

No statistical analyses for this end point

Secondary: Benzodiazepine Withdrawal Symptom Questionnaire (BWSQ) Total Score for Self-Assessment of Withdrawal Symptoms on Day 17

End point title	Benzodiazepine Withdrawal Symptom Questionnaire (BWSQ) Total Score for Self-Assessment of Withdrawal Symptoms on Day 17

End point description:

The BWSQ is a 20 symptom self-report questionnaire to investigate withdrawal symptoms. Total scores can range from 0-40 with higher scores indicating greater severity of symptoms. Subjects rate the degree to which they are experiencing each symptom as either "No," "Yes-moderate" or "Yes-severe". The questionnaire has been shown to be reliable and to have acceptable construct validity in assessing withdrawal symptoms. Total scores can range from 0-40 with higher scores indicating greater severity of symptoms. SAS included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. Here, N (number of subjects analyzed) signifies number of subjects evaluable for this endpoint. One subject who was randomized to JNJ-42847922 10 mg dose group received 5 mg of JNJ-42847922. This subject was summarized under the 5 mg dose group for safety analyses.

End point type	Secondary

End point timeframe:

Day 17

End point values	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg	JNJ-42847922 20 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	58	54	56	51
Units: Unit on a Scale				
arithmetic mean (standard deviation)	1.5 (± 2.58)	1.2 (± 1.90)	2.0 (± 3.44)	1.5 (± 2.93)

End point values	Zolpidem			
Subject group type	Subject analysis set			
Number of subjects analysed	55			
Units: Unit on a Scale				
arithmetic mean (standard deviation)	2.0 (± 3.10)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:	
Up to Day 17	

Adverse event reporting additional description:

Safety analysis set included all subjects who were randomly assigned to study drug and received at least 1 dose of study drug. One subject who was randomized to JNJ-42847922 10 mg dose group received 5 mg of JNJ-42847922. This subject was summarized under the 5 mg dose group for safety analyses.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	21.1

Reporting groups

Reporting group title	Placebo

Reporting group description:

Subjects received matching placebo as 2 oral capsules for 14 consecutive nights from Day 1 to Day 14.

Reporting group title	JNJ-42847922 5 mg

Reporting group description:

Subjects received JNJ-42847922 5 milligram (mg) dose as two 2.5 mg oral capsules for 14 consecutive nights from Day 1 to Day 14.

Reporting group title	JNJ-42847922 10 mg

Reporting group description:

Subjects receive JNJ-42847922 10 mg as one 10 mg oral capsule and one placebo capsule for 14 consecutive nights from Day 1 to Day 14.

Reporting group title	JNJ-42847922 20 mg

Reporting group description:

Subjects received JNJ-42847922 20 mg as one 20 mg oral capsule and one placebo capsule for 14 consecutive nights from Day 1 to Day 14.

Reporting group title	Zolpidem

Reporting group description:

Subjects received Zolpidem 5 mg as one 5 mg capsule plus one placebo capsule or 10 mg Zolpidem as two 5 mg oral capsules for 14 consecutive nights from Day 1 to Day 14.

Serious adverse events	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 75 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Nervous system disorders			
Cerebral Haemorrhage			
subjects affected / exposed	0 / 75 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cognitive Disorder			

subjects affected / exposed	0 / 75 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	JNJ-42847922 20 mg	Zolpidem	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 71 (1.41%)	1 / 73 (1.37%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Nervous system disorders			
Cerebral Haemorrhage			
subjects affected / exposed	1 / 71 (1.41%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cognitive Disorder			
subjects affected / exposed	0 / 71 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Placebo	JNJ-42847922 5 mg	JNJ-42847922 10 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	22 / 75 (29.33%)	16 / 72 (22.22%)	10 / 73 (13.70%)
Nervous system disorders			
Disturbance in Attention			
subjects affected / exposed	4 / 75 (5.33%)	2 / 72 (2.78%)	1 / 73 (1.37%)
occurrences (all)	4	2	1
Dizziness			
subjects affected / exposed	1 / 75 (1.33%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences (all)	1	0	0
Headache			
subjects affected / exposed	8 / 75 (10.67%)	7 / 72 (9.72%)	4 / 73 (5.48%)
occurrences (all)	8	8	6
Somnolence			

subjects affected / exposed	1 / 75 (1.33%)	1 / 72 (1.39%)	0 / 73 (0.00%)
occurrences (all)	1	1	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	8 / 75 (10.67%)	4 / 72 (5.56%)	3 / 73 (4.11%)
occurrences (all)	8	4	3
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	3 / 75 (4.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences (all)	4	0	0
Nausea			
subjects affected / exposed	2 / 75 (2.67%)	1 / 72 (1.39%)	2 / 73 (2.74%)
occurrences (all)	2	1	2
Psychiatric disorders			
Restlessness			
subjects affected / exposed	4 / 75 (5.33%)	0 / 72 (0.00%)	2 / 73 (2.74%)
occurrences (all)	4	0	2
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	3 / 75 (4.00%)	1 / 72 (1.39%)	1 / 73 (1.37%)
occurrences (all)	4	1	1
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	1 / 75 (1.33%)	4 / 72 (5.56%)	1 / 73 (1.37%)
occurrences (all)	1	4	1
Urinary Tract Infection			
subjects affected / exposed	4 / 75 (5.33%)	0 / 72 (0.00%)	1 / 73 (1.37%)
occurrences (all)	4	0	1

Non-serious adverse events	JNJ-42847922 20 mg	Zolpidem	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 71 (18.31%)	21 / 73 (28.77%)	
Nervous system disorders			
Disturbance in Attention			
subjects affected / exposed	1 / 71 (1.41%)	4 / 73 (5.48%)	
occurrences (all)	1	4	
Dizziness			

subjects affected / exposed	0 / 71 (0.00%)	5 / 73 (6.85%)
occurrences (all)	0	7
Headache		
subjects affected / exposed	6 / 71 (8.45%)	8 / 73 (10.96%)
occurrences (all)	8	10
Somnolence		
subjects affected / exposed	4 / 71 (5.63%)	4 / 73 (5.48%)
occurrences (all)	4	5
General disorders and administration site conditions		
Fatigue		
subjects affected / exposed	2 / 71 (2.82%)	2 / 73 (2.74%)
occurrences (all)	2	2
Gastrointestinal disorders		
Diarrhoea		
subjects affected / exposed	1 / 71 (1.41%)	4 / 73 (5.48%)
occurrences (all)	1	4
Nausea		
subjects affected / exposed	0 / 71 (0.00%)	5 / 73 (6.85%)
occurrences (all)	0	5
Psychiatric disorders		
Restlessness		
subjects affected / exposed	2 / 71 (2.82%)	1 / 73 (1.37%)
occurrences (all)	2	1
Musculoskeletal and connective tissue disorders		
Myalgia		
subjects affected / exposed	0 / 71 (0.00%)	4 / 73 (5.48%)
occurrences (all)	0	4
Infections and infestations		
Nasopharyngitis		
subjects affected / exposed	0 / 71 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Urinary Tract Infection		
subjects affected / exposed	1 / 71 (1.41%)	0 / 73 (0.00%)
occurrences (all)	1	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
22 January 2018	The overall reason for the amendment is to update exclusion criteria, based on Health Authority request to ensure breastfeeding women are excluded from the study and to provide more detail on certain clinical conditions that are contra-indicated for zolpidem use.
24 April 2018	To add results of the male and female rat fertility studies; To exclude further enrollment of women of childbearing potential (WOCBP); In addition, other minor changes and clarifications related to study procedures were made.
25 July 2018	To remove the interim analysis from the protocol; To change a secondary objective to an exploratory objective; To change an exploratory correlation analysis; To clarify the inclusion criteria regarding the follicle stimulating hormone (FSH) level threshold for postmenopausal women and the time spent in bed as well as the exclusion criterion for the threshold of ECG abnormalities; To add abnormal (vivid) dreams as an adverse event of special interest; In addition, other minor changes and clarifications related to study procedures were made.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

 None reported