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PROPRIETARY DRUG NAME[®]/GENERIC DRUG NAME: Zolpidem

THERAPEUTIC AREA AND FDA APPROVED INDICATIONS: See USPI.

NATIONAL CLINICAL TRIAL NO.: NCT00716521

PROTOCOL NO.: A9001390

PROTOCOL TITLE: Subject- and Investigator-Blinded, Sponsor-Open, Randomized, Single-Dose, Placebo-Controlled, 3-Way Crossover Study to Study Effect of Treatment With Oral Zolpidem on Polysomnography and Actigraphy Measures in Healthy Volunteers

Study Center: This study was conducted at 1 study center in the United States.

Study Initiation and Completion Dates: 21 July 2008 to 12 October 2008.

Phase of Development: Phase 1

Study Objectives: The objectives of this study were:

- Evaluate the effect of 2 doses of zolpidem vs. placebo on the polysomnography (PSG) profile in the clinical research unit (CRU) setting;
- Evaluate the effects of zolpidem vs. placebo on ambulatory actigraphy measurements in the CRU and compare the actigraphy measurements (without zolpidem) in the home environment;
- Estimate the accuracy of the Respironics Actiwatch™ and the Armband compared to PSG for estimating global sleep parameters (latency to persistent sleep [LPS], total sleep time [TST], wake after sleep onset [WASO], sleep efficiency); and
- Compare the Actiwatch™ to the Armband with respect to the ability to detect the effects of oral single dose zolpidem on global sleep parameters.

METHODS

Study Design: This study was an investigator- and subject-blinded (sponsor open), randomized, placebo-controlled, 3-way crossover study with 3 treatments in healthy male and female subjects. Subjects received a single oral dose of each of the 3 treatments

(A: placebo, B: zolpidem 5 mg, and C: zolpidem 10 mg) with a 24-hour interval between treatments. Treatments were given on consecutive days. An initial run-in period in which no treatment was given preceded the 3 treatment periods. A total of 12 subjects were to be randomized to each of 6 treatment sequences in a 1:1:1:1:1:1 ratio in cohorts of 3 subjects each. Dropouts were to be replaced at the discretion of the sponsor.

Actigraphy measurements (Armband and Actiwatch) were collected for 5 nights in-home prior to subject admission to the CRU. Following admission, PSG data were collected on 4 consecutive nights (4 nights total). In addition, the Armband and Actiwatch were worn on each night of PSG measurements. After completion of the PSG and actigraphy data collection phase, subjects were discharged from the study.

Number of Subjects (Planned and Analyzed): Although 12 subjects were planned, 1 subject had a Day 0 PSG recording that made the subject ineligible for study participation. No alternates were enrolled, therefore only 11 subjects were included in the study. All of which crossed over to receive all 3 study treatments (placebo, zolpidem 5 mg, and zolpidem 10 mg).

Diagnosis and Main Criteria for Inclusion: This study included healthy male and female subjects between the ages of 18 to 55 years, inclusive, with a body mass index (BMI) of approximately 18 to 30 kg/m² and a total body weight >50 kg (110 pounds). Subjects had to have a self reported sleep/wake schedule for a typical week night (ie, Monday-Thursday) as follows: typical waking time at approximately 0500 to 0800 hours, typical time for sleep onset at approximately 2200 to 2400 hours, and typical TST of approximately 6 to 10 hours.

Study Treatment: Three treatments were used, as shown in Table S1. Study treatment A (placebo) was obtained through Pfizer's Pharmaceutical Sciences department. Study treatments B (zolpidem 5 mg) and C (zolpidem 10 mg) were obtained directly from the site pharmacy as the commercially available formulation. The pharmacist was not blinded to study medication. However, the subjects and all other site personnel, including the PSG technicians, were blinded.

On Day 0, no drug or placebo was given. On Day 1 of Periods 1-3, zolpidem (5 mg or 10 mg orally) or placebo was given once daily at approximately 2200 hours in a randomized 3-way cross-over design.

Table S1. Study Treatments

Regimen	Study Treatment
A	Placebo administered as a single oral dose on Day 1 of Periods 1, 2 or 3
B	Zolpidem 5 mg administered as a single oral dose on Day 1 of Periods 1, 2 or 3
C	Zolpidem 10 mg administered as a single oral dose on Day 1 of Periods 1, 2 or 3

Efficacy Evaluations: No efficacy evaluations were performed in this study.

Outcomes Research: Primary evaluations included PSG recordings, actigraphy measurements, Leeds Sleep Evaluation Questionnaire (LSEQ) measures, and the subjective Sleep Questionnaire (SSQ).

PSG Recordings: PSG recordings were performed on Day 0 and Day 1 of each period. PSG recordings were performed in the CRU. Respiration rate and nasal monitoring were also recorded. Recording began at approximately 2200 hours and continued until 0700 hours or terminal awakening. PSG records were scored by a central reader according to Rechtschaffen and Kales criteria. PSG recordings from Day 0 were assessed by a central reader prior to dosing on Day 1 to rule out any primary sleep disorders not disclosed at Screening.

Actigraphy Measurements: Two actigraphy measurement devices were used in this study: the Respironics Actiwatch™ and the Body Media Senseware® Armband Pro 3. Actiwatch was to be worn like a watch on the right arm. It provided a measure of activity which the Respironics algorithm converted to “scoring” of sleep versus awake for each minute during the night. Armband was to be worn on the back of the upper right arm (same side as Actiwatch). It monitored activity and heat exchange between the body and ambient air. The Bodymedia algorithm converted the activity and thermodynamic data into a “score” of sleep versus awake for each minute during the night.

At home, each subject was to wear both actigraphy measurement devices on the right arm during the 5 nights before they entered the CRU for the PSG study. They were to put the devices on before going to bed and take them off after they got out of bed in the morning.

At the CRU, each subject continued to wear the same 2 devices on the right arm during each night of PSG measurements in the CRU. At the end of the last PSG measurement, all of the data from the devices was downloaded for analysis. Subjects could not take the devices with them on discharge from the study.

LSEQ Measures: The LSEQ was a subject-reported outcome measure consisting of 10 visual analog scale items that assessed 4 areas of sleep: the ease of getting to sleep (GTS), the perceived quality of sleep (QOS), the ease of awakening from sleep (AFS), and early morning behavior following wakefulness (BFW). Subjects were asked to compare the sleep experienced during the study period with the sleep they normally experience. The questionnaire took approximately 3-5 minutes for the subject to complete. Each of the questions was a visual analog scale that measured 100 mm in length. The length of the segment that the subject marked was measured to the nearest millimeter, and that score, ranging from 0-100, was recorded. The LSEQ was administered at approximately 30 minutes post terminal awakening. The LSEQ was considered an exploratory endpoint, therefore, LSEQ data were not summarized and are presented in a listing only.

SSQ Measures: The SSQ was designed to capture subjective evaluation of sleep behavior in subjects with disrupted sleep. The questionnaire asked subjects to report latency (how long it took them to fall asleep), how many hours they slept, the number of times they woke up, the total wake time after sleep onset, and then to rate the quality of their sleep for the previous night. The SSQ was administered approximately 30 minutes post terminal awakening in the CRU on Day 1 of each period. For Question 4, site personnel measured the distance from the left-hand anchor to the subject’s mark, and recorded the score in mm. The SSQ was considered an exploratory endpoint, therefore, SSQ data were not summarized and are presented in a listing only.

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Safety Evaluations: Safety evaluations included adverse events (AEs), safety laboratory tests, vital signs (pulse rate and blood pressure), and 12-lead ECGs.

Hematology, blood chemistry, urinalysis, and follicle-stimulating hormone testing (post-menopausal women) were obtained at Screening. Urine cotinine and a urine drug screen were obtained at Screening and Day 0. The minimum requirements for drug screening included: cocaine, tetrahydrocannabinol, opiates, benzodiazepines, and amphetamines. A pregnancy test was conducted at Screening, Day 0, and at the end of Period 3 only. Results of the Day 0 pregnancy test must have been negative in order for female subjects of childbearing potential to receive study medication on Day 1.

Single supine vital signs were obtained at Screening, Day 0, and Day 1 at 9.5 hours postdose (Periods 1-3). A 12-lead ECG was conducted at Screening only. AEs were evaluated throughout the study.

Statistical Methods: Analyses were conducted on the full analysis set (FAS) population. The FAS consisted of all subjects with sleep data on at least 1 dose of zolpidem and on placebo.

Each of the 3 sleep/activity monitor instruments (PSG, Actiwatch, and Armband) generated data on a by-epoch basis. The by-epoch source data were summarized by the vendor or in-house, and the primary and secondary endpoints were included in a database.

There were 3 primary endpoints. Each primary endpoint was measured by each of the 3 techniques. Each primary endpoint included a summary of data collected over the entire sleep event period, and this was provided to the database. The primary endpoints were:

1. LPS in minutes.
2. WASO in minutes.
3. Sleep efficiency (%).

There were measurements for 1 of each endpoint for each instrument for each night in the CRU. There were additional data for each night that the Actiwatch and Armband were worn in the at-home period prior to admission to the CRU.

There were 2 secondary endpoints. Each secondary endpoint was measured by each of the 3 techniques. Each secondary endpoint included a summary of data collected over the entire sleep event period, and this was provided to the database. The secondary endpoints were:

1. Total sleep time (TST) in minutes.
2. Total number of awakenings after sleep onset (integer).

There were measurements for 1 of each endpoint for each instrument for each night in the CRU. There were additional data for each night that the Actiwatch and Armband were worn in the at-home period prior to admission to the CRU.

The 3 primary endpoints and 1 of the 2 secondary endpoints, TST, are continuous measures. The total number of awakenings is integer data. The treatment effect of dose on the continuous endpoints was assessed using a repeated measures mixed effects model containing factors for subject (random), sequence, and dose. Each endpoint was analyzed separately for data collected with each measurement instrument. Least squares mean response and estimated treatment effect size ([drug –Placebo]/standard error) was displayed for each endpoint and each measurement instrument. The estimated treatment effect size could be used to predict required sample sizes for future studies in the CRU. By-subject plots with dose on the horizontal axis and response on the vertical axis were generated to complement the analysis.

The data for the total number of awakenings after sleep onset was to be analyzed in 1 of 2 ways, depending on the appropriateness of the data. If no subject in either zolpidem group had more than 2 awakenings, the data would have been dichotomized to no awakenings or at least 1 awakening, and an extension to McNemar's test could have been used to compare the proportions of subjects who awaken during the night. Since this was not the case in subjects treated with zolpidem, repeated awakenings in the CRU were assessed using descriptive statistics only, and a table showing the distribution of the number of awakenings on each dose was produced. A by-subject plot of the number of awakenings by dose was generated, including the run-in first night data.

The relationship between the same endpoint measured with different instruments was to be assessed with summary measures of association. Pairwise Pearson correlations of the data were used to summarize agreement of the measurement techniques. This analysis could include the run-in first night in the CRU, providing 4 measures for each subject instead of 3.

Standard safety reports for standard safety endpoints were produced.

RESULTS

Subject Disposition and Demography: A total of 11 subjects were assigned to study treatment. All subjects completed the study and were analyzed for efficacy (Armband, SSQ, Actiwatch, PSG, and LSEQ) and safety (AEs and vital signs). The mean (standard deviation [SD]) age of the 11 subjects was 36.5 years (8.5) and the mean (SD) BMI was 26.2 kg/m² (3.4).

Efficacy Results: No efficacy evaluations were performed in this study.

Outcomes Research Results: One objective of this study was to evaluate the effect of 2 different doses of zolpidem versus placebo on the PSG profile in the CRU setting. No statistically significant difference was observed in the adjusted arithmetic mean for LPS in either the 5 or 10 mg zolpidem treatments versus placebo in the PSG profile. A statistically significant difference (defined as $\alpha < 0.1$) was observed for both treatments versus placebo in sleep efficiency ($p = 0.0711$ and $p = 0.0268$ for the 10 mg and 5 mg zolpidem, respectively), TST ($p = 0.0711$ and $p = 0.0268$ for the 10 mg and 5 mg zolpidem, respectively), and WASO ($p = 0.0559$ and $p = 0.0363$ for the 10 mg and 5 mg zolpidem, respectively). Descriptive statistics for PSG data are presented in Table S2.

Table S2. Descriptive Statistics for PSG Data

Parameter (units)	Placebo (N ^b =11)	Zolpidem 5 mg (N ^b =11)	Zolpidem 10 mg (N ^b =11)
Awakening NO			
N ^a	11	11	11
Arithmetic mean (SD)	16.2 (10.07)	20.8 (9.70)	15.5 (10.13)
Range	3-41	7-37	3-33
LPS (min)			
N ^a	11	11	11
Arithmetic mean (SD)	21.23 (13.503)	14.05 (8.522)	21.23 (26.592)
Range	3.0-47.5	1.5-28.0	1.0-87.5
Sleep efficiency (%)			
N ^a	11	11	11
Arithmetic mean (SD)	81.71 (14.608)	89.65 (4.791)	88.04 (8.889)
Range	47.6-94.1	80.9-97.4	71.4-96.0
TST (min)			
N ^a	11	11	11
Arithmetic mean (SD)	392.23 (70.115)	430.32 (22.996)	422.59 (42.665)
Range	229.0-452.0	389.0-468.0	343.0-461.0
WASO (min)			
N ^a	11	11	11
Arithmetic mean (SD)	69.05 (66.104)	36.77 (20.628)	39.86 (35.626)
Range	20.0-238.0	6.5-70.5	8.5-134.0

Awakening NO = total number of awakenings after sleep onset; SD = standard deviation; LPS = latency to persistent sleep; WASO = wake after sleep onset; TST = total sleep time.

^a Number of subjects contributing to the mean.

^b Total number of subjects in the treatment group in the indicated population.

Another objective of the study was to evaluate the effects of zolpidem versus placebo on ambulatory actigraphy measurements in the CRU and compare the actigraphy measurements (without zolpidem) in the home environment. Descriptive statistics for Actiwatch and Armband data in the CRU and in the home environment are presented in Table S3 and Table S4, respectively.

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Table S3. Descriptive Statistics for Actiwatch and Armband Data in the Clinical Research Unit Environment

Parameter (units)	Actiwatch			Armband		
	Placebo (N ^b =11)	Zolpidem 5 mg (N ^b =11)	Zolpidem 10 mg (N ^b =11)	Placebo (N ^b =11)	Zolpidem 5 mg (N ^b =11)	Zolpidem 10 mg (N ^b =11)
Awakening NO						
N ^a	11	11	11	11	11	11
Arithmetic mean (SD)	5.0 (3.55)	4.6 (3.47)	3.8 (4.05)	4.0 (3.92)	4.7 (3.61)	3.4 (2.50)
Range	0-11	0-12	0-11	1-15	0-10	0-7
LPS (min)						
N ^a	11	11	11	11	11	11
Arithmetic mean (SD)	26.36 (30.878)	30.73 (36.601)	17.55 (26.771)	14.91 (9.322)	22.55 (19.705)	24.27 (28.869)
Range	0.0-75.0	0.0-90.0	0.0-73.0	2.0-27.0	0.0-65.0	0.0-97.0
Sleep efficiency (%)						
N ^a	11	11	11	11	11	11
Arithmetic mean (SD)	85.81 (10.210)	88.07 (7.232)	90.95 (5.223)	90.78 (11.897)	94.15 (5.299)	91.96 (9.356)
Range	64.5-97.4	78.6-97.3	83.2-97.6	66.9-99.6	85.1-100.0	69.3-100.0
TST (min)						
N ^a	11	11	11	11	11	11
Arithmetic mean (SD)	428.64 (43.562)	433.18 (19.999)	444.18 (17.400)	416.36 (57.467)	430.09 (30.290)	427.64 (52.256)
Range	311.0-466.0	394.0-462.0	400.0-460.0	294.0-471.0	377.0-481.0	331.0-525.0
WASO (min)						
N ^a	11	11	11	11	11	11
Arithmetic mean (SD)	40.73 (31.161)	22.64 (10.462)	24.64 (16.083)	41.55 (56.199)	26.36 (23.295)	37.36 (43.894)
Range	10.0-113.0	9.0-44.0	5.0-62.0	2.0-169.0	0.0-67.0	0.0-147.0

Awakening NO = total number of awakenings after sleep onset; SD = standard deviation; LPS = latency to persistent sleep; WASO = wake after sleep onset; TST = total sleep time.

^a Number of subjects contributing to the mean.

^b Total number of subjects in the treatment group in the indicated population.

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Table S4. Descriptive Statistics for Actiwatch and Armband Data in the Home Environment and Run-In Day

Parameter (units)	Actiwatch			Armband		
	Day -5	Day -3	Day 0 (Run-in)	Day -5	Day -3	Day 0 (Run-in)
Awakening NO						
N ^a	10	11	11	11	11	11
Arithmetic mean (SD)	2.8 (4.02)	2.4 (2.62)	4.8 (4.71)	4.5 (3.56)	4.1 (3.14)	2.8 (3.03)
Range	0-12	0-9	0-14	0-11	0-9	0-10
LPS (min)						
N ^a	10	11	11	11	11	11
Arithmetic mean (SD)	6.7 (6.57)	9.2 (9.73)	17.5 (21.4)	13.2 (16.09)	12.3 (14.23)	9.6 (7.1)
Range	1-20	0-25	0-77	0-52	0-40	0-24
Sleep efficiency (%)						
N ^a	10	11	11	11	11	11
Arithmetic mean (SD)	89.9 (7.34)	89.9 (3.62)	89.7 (5.97)	90.8 (7.38)	86.4 (12.2)	95.2 (5.45)
Range	77.2-95.8	83.4-95	77.4-99.5	81.4-99.8	60-100	87-100
TST (min)						
N ^a	10	11	11	11	11	11
Arithmetic mean (SD)	392.7 (98.52)	348.9 (70.4)	449.3 (38.14)	387.8 (74.05)	319.3 (106.35)	427.4 (94.77)
Range	266-573	202-427	385-515	249-527	204-493	168-518
WASO (min)						
N ^a	10	11	11	11	11	11
Arithmetic mean (SD)	29.3 (18.89)	19.5 (7.02)	25 (14.52)	37.8 (32.61)	49.5 (47.71)	22.4 (26.49)
Range	10-60	7-30	2-52	0-97	0-166	0-66

Awakening NO = total number of awakenings after sleep onset; SD = standard deviation; LPS = latency to persistent sleep; WASO = wake after sleep onset; TST = total sleep time.

^aNumber of subjects contributing to the mean.

In general, Armband and Actiwatch results during home-monitoring days were similar to results observed with placebo treatment in the CRU.

In the CRU environment, Actiwatch detected statistically significant differences after treatment with zolpidem 10 mg compared to placebo in sleep efficiency ($p = 0.0279$). Actiwatch also detected statistically significant differences after treatment with 5 and 10 mg zolpidem compared to placebo in WASO ($p = 0.0522$ and $p = 0.0310$ for 10 and 5 mg zolpidem treatments, respectively). No statistically significant differences were observed with the use of Armband after treatment with 5 and 10 mg zolpidem compared to placebo.

A statistical comparison of the Actiwatch and Armband measurement devices to PSG indicates that actigraphy (Armband and Actiwatch) and PSG are similar in their ability to accurately detect LPS; however, both actigraphy measurement devices overestimated WASO. Actiwatch estimated sleep efficiency accurately, and Armband estimated TST accurately.

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To evaluate the concordance of Actiwatch and Armband compared to PSG for estimating global sleep parameters (LPS, TST, WASO, and sleep efficiency), correlations between measurement devices were evaluated and are presented in Table S5. Both Actiwatch and Armband had moderate to strong correlations with PSG for sleep efficiency and WASO, and Armband measurements correlated with PSG for TST. A correlation was observed between Actiwatch and Armband for sleep efficiency, TST, and WASO, but not LPS.

Table S5. Correlations Between Measurement Devices

Parameter (units)	Devices Compared	N	Pearson Correlation	P-value
LPS (min)	PSG versus Actiwatch	11	0.00002	0.9999
	PSG versus Armband	11	-0.17365	0.2596
	Actiwatch versus Armband	11	0.15025	0.3303
WASO (min)	PSG versus Actiwatch	11	0.62892	<0.0001
	PSG versus Armband	11	0.71536	<0.0001
	Actiwatch versus Armband	11	0.72261	<0.0001
Sleep Efficiency (%)	PSG versus Actiwatch	11	0.42160	0.0044
	PSG versus Armband	11	0.65836	<0.0001
	Actiwatch versus Armband	11	0.53915	0.0002
TST (min)	PSG versus Actiwatch	11	0.18937	0.2183
	PSG versus Armband	11	0.31605	0.0366
	Actiwatch versus Armband	11	0.52527	0.0003

LPS = latency to persistent sleep; WASO = wake after sleep onset; TST = total sleep time.

The final objective of this study was to compare Actiwatch to Armband with respect to the ability to detect the effects of a single oral dose of zolpidem on global sleep parameters (LPS, TST, WASO, and sleep efficiency). PSG detected statistically significant differences between both doses of zolpidem and placebo treatment in 3 of the 4 study parameters evaluated (sleep efficiency, TST, and WASO). Actiwatch was able to detect statistically significant differences in subjects after treatment with zolpidem compared to placebo in 2 of the 4 study parameters evaluated (sleep efficiency [10 mg dose only] and WASO [both doses]) while Armband was unable to detect statistically significant differences in any study parameter.

A comparison of the endpoint values obtained from the Actiwatch or the Armband against the values determined by PSG show that neither device is a suitable substitute for PSG which is the gold-standard description of sleep. The estimates of the sleep endpoints provided by the Actiwatch and the Armband are dependent upon each device's algorithm that converts the sensor data into sleep endpoints. This study showed that the Actiwatch algorithm provided endpoints that were more sensitive to the effects of zolpidem than were the endpoints provided by the Armband algorithm. However, the set of PSG, Armband, and Actiwatch data provided by this study will be very valuable for designing new actigraphy algorithms that provide endpoints that are more useful for drug development.

Safety Results: No subjects temporarily discontinued study treatment, had a dose reduction, or permanently discontinued the study due to an AE. All females had negative pregnancy tests at the end of Period 3 with the exception of 1 subject who was amenorrheic for 2 years and had a serum FSH consistent with the post-menopausal normal range at Screening. There were no clinically significant laboratory or ECG abnormalities at Screening for any subject

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randomized in this study. During treatment with placebo, 1/11 subjects experienced 2 AEs. During treatment with 5 and 10 mg zolpidem, 2/11 subjects experienced 4 AEs, and 1/11 subjects experienced 1 AE, respectively. All AEs reported in this study were considered treatment related. No subject experienced a serious or severe AE. All AEs were represented by a single occurrence with the exception of abnormal dreams which occurred in 2/11 subjects during treatment with 5 mg zolpidem. No clinically significant abnormalities were observed in vital signs.

CONCLUSIONS:

In healthy volunteers who report no sleep disturbances:

- In the CRU environment, PSG detected statistically significant (defined as $\alpha < 0.1$) differences between both the 5 and 10 mg doses of zolpidem and placebo treatment in 2 of 3 primary PSG measures, sleep efficiency and WASO, and in 1 of 2 secondary measures, TST. No effects were seen on LPS (primary measure) and number of awakenings (secondary measure).
- In the CRU environment, the use of Actiwatch detected statistically significant differences between zolpidem and placebo treatment in sleep efficiency (10 mg zolpidem treatment only), and WASO (5 and 10 mg zolpidem treatments) while no statistically significant differences were observed between treatments with the use of Armband in any study parameter. In general, Armband and Actiwatch results were similar in the home and during the placebo night CRU (without zolpidem) environments.
- Both Actiwatch and Armband measurements had moderate to strong correlations with PSG for sleep efficiency and WASO, and Armband measurements correlated with PSG for TST. A correlation was observed between Actiwatch and Armband for sleep efficiency, TST, and WASO, but not LPS.
- PSG detected statistically significant differences between both doses of zolpidem and placebo treatments in 3 of the 4 study parameters evaluated (sleep efficiency, TST, and WASO). Actiwatch was able to detect statistically significant differences in subjects after treatment with zolpidem compared to placebo in 2 of the 4 study parameters evaluated (sleep efficiency [10 mg dose only] and WASO [both doses]), while Armband was unable to detect statistically significant differences in any study parameter. These results indicate that the Actiwatch algorithm provided endpoints that were more sensitive to the effects of zolpidem than were the endpoints provided by the Armband algorithm.

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