POSTER #221

Consistency in effect of elinzanetant on wakefulness after sleep onset across subjective and objective measures: post hoc analysis of the Phase II NIRVANA pilot study in postmenopausal women with sleep disturbance

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INTRODUCTION

- Sleep disturbance is frequently reported among menopausal women and can be disruptive, impacting quality of life.[1,2]
- There is limited evidence that exisiting treatments are effective in women with menopause-associated sleep disturbance.[3]
- Elinzanetant, a dual neurokinin (NK)1 and NK3 receptor antagonist, has previously demonstrated improvements in patient-reported outcomes for sleep disturbance in the pivotal OASIS studies.[4,5]
- The Phase II NIRVANA trial evaluated elinzanetant's effects on sleep parameters focusing on wakefulness after sleep onset (WASO), using both objective (in-lab polysomnography [PSG], continuous contactless home sleep monitor [Sleepiz One+]) and subjective (Sleep Diary) measures in postmenopausal women with moderate-to-severe vasomotor symptoms (VMS) and sleep disturbance.

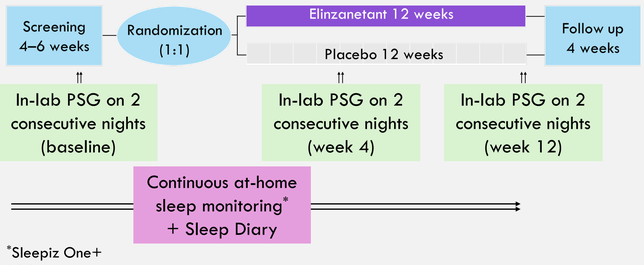
OBJECTIVE

- To examine numerical changes in WASO over 12 weeks of treatment with elinzanetant across three modalities (in-lab PSG, continuous contactless home sleep monitoring [Sleepiz One+]), and nightly Sleep Diary).

METHODS

- A total of 110 postmenopausal women (mean [standard deviation; SD] age: 54.8 [4.6] years) with PSG-confirmed sleep disturbance (WASO ≥30 minutes) and ≥20 moderate-to-severe VMS/week were randomized to elinzanetant 120 mg (n=55) or placebo (n=55) once daily for 12 weeks (**Figure 1**).

Figure 1. NIRVANA trial design

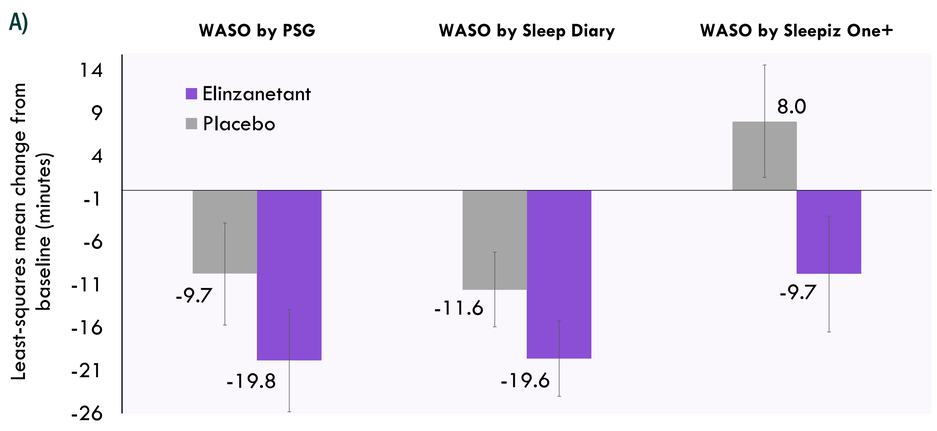


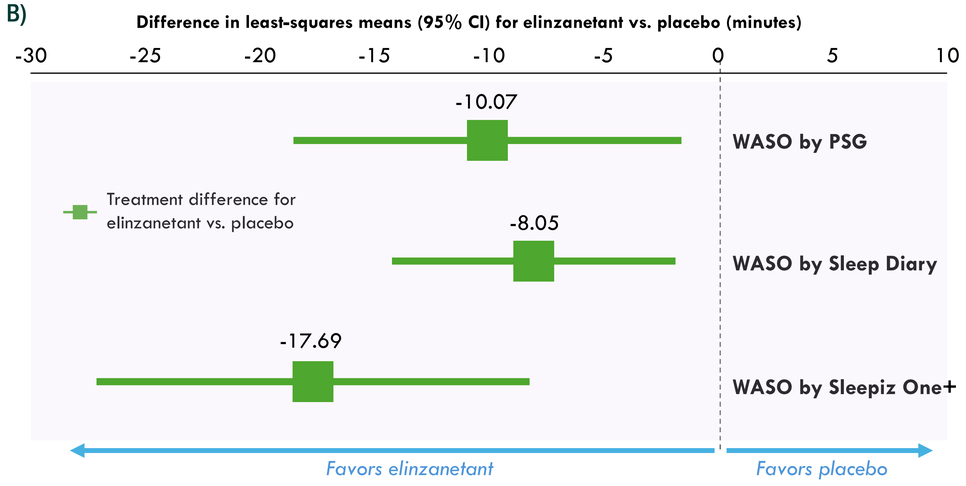
*Sleepiz One+
PSG, polysomnography.

- Sleep disturbance was assessed using in-lab PSG and a patient-reported Sleep Diary for all participants, and with the Sleepiz One+ (Sleepiz AG, Zurich, Switzerland) in a sub-sample (n=66; elinzanetant: n=33, placebo: n=33).
- PSG was conducted at baseline, week 4, and week 12 (two consecutive nights per time point). Sleepiz One+ and Sleep Diary data were collected nightly throughout the 12-week treatment period.
- Data were analyzed on the original observed units to provide consistency in data presentation across measures. A post hoc random coefficient model estimated the treatment effects on WASO over the 12-week treatment period across all available nights for each method.
- Numerical trends were exploratory measured due to small sample size.

RESULTS

Figure 2. A) Least-squares mean change (95% CI) from baseline for elinzanetant and placebo and B) difference in least-squares means for elinzanetant vs. placebo in WASO by PSG, Sleep Diary, and Sleepiz One+ over the 12-week treatment period





CI, confidence interval; PSG, polysomnography; WASO, wakefulness after sleep onset.

- **PSG:** mean (SD) WASO at baseline was 74.7 (34.8) minutes in the elinzanetant group and 82.8 (34.4) minutes in the placebo group.
- **Sleep Diary:** mean (SD) WASO at baseline was 42.4 (25.7) minutes in the elinzanetant group and 45.5 (25.6) minutes in the placebo group.
- **Sleepiz One+:** mean (SD) WASO at baseline was 77.7 (52.6) minutes in the elinzanetant group and 61.7 (27.6) minutes in the placebo group.
- Elinzanetant reduced WASO across all three modalities (**Figure 2A**). These reductions were numerically greater than the changes observed with placebo over the 12-week treatment period (**Figure 2B**).

CONCLUSIONS

In this post hoc analysis, greater reductions in WASO were seen in the elinzanetant arm compared with placebo across all assessment modalities.

NIRVANA was the first study to integrate gold-standard PSG, continuous home sleep monitoring, and patient-reported outcomes to assess treatment effects on WASO in postmenopausal women with VMS and sleep disturbance.

These results directionally align with improvements in patient-reported sleep disturbance shown in the previous OASIS trials, although the small sample size and exploratory design warrant cautious interpretation.

REFERENCES

1. Maki PM, et al. Menopause 2024;31:724–33; 2. DePree B, et al. Menopause 2023;30(9):887–97; 3. Schaedel Z, et al. Post Reprod Health 2021;27(4):209–14; 4. Pinkerton JV, et al. JAMA 2024;332:1343–54; 5. Cardoso F, et al. N Engl J Med 2025;393(8):753–63.

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