

# Hot flash drug shows significant benefits in clinical trials

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The investigational drug elinzanetant significantly reduces the frequency and severity of hot flashes associated with menopause while improving women's quality of life, according to new UVA Health research

[published](#) in the *Journal of the American Medical Association (JAMA)* shows.

The nonhormonal drug, containing no estrogen, was tested in two phase 3 trials, Oasis 1 and 2, at dozens of locations in the United States, Europe, and Israel, including UVA Health. Postmenopausal women ages 40-65 with moderate to severe hot flashes were randomized to receive either 120 mg of elinzanetant daily for 26 weeks or a harmless matching placebo for 12 weeks followed by 14 weeks on elinzanetant.

The women who received elinzanetant reported rapid improvements in their symptoms and quality of life. The trials revealed statistically significant reductions in hot flash frequency and severity within the first week in both trials. At the same time, [sleep quality](#) and overall quality of life improved in both trials by week 12.

"The effectiveness for relief of hot flashes in highly symptomatic women, along with improvements in sleep and mood across multiple trials and favorable safety profile of elinzanetant, suggests it has potential as a non-estrogen treatment for women with bothersome menopausal symptoms," said researcher JoAnn V. Pinkerton, MD, UVA Health's director of midlife health. "Elinzenetant is a dual neurokinin receptor antagonist in testing, meaning it works on two receptors in the brain to improve hot flashes, night sweats sleep, and overall mood."

## Hot flash treatment

Hot flashes are caused by decreased estrogen levels during menopause, and for some women, for years after. While there are existing [treatment options](#), such as [hormone therapy](#), some women cannot tolerate them or do not wish to take them because of potential side effects or contraindications. Because of that, the researchers say, there is a need for a new, effective, nonhormonal alternative.

"There is a huge unmet need for new treatments for hot flashes. Menopausal women who cannot take hormone therapy due to [health issues](#) or choose not to take it need more non-estrogen options to improve their burdensome hot flashes and sweats, which have been shown to affect workplace productivity and relationships both at work and home," said Pinkerton, professor of obstetrics and gynecology at the University of Virginia School of Medicine and executive director emeritus of the North American Menopause Society.

"Sleep disturbances are one of the most bothersome symptoms reported by menopausal women and can impact mood fatigue, emotional lability, work productivity, quality of life."

Pinkerton and her colleagues tested elinzanetant in the double-blinded Oasis studies to see if it could safely and effectively offer a new alternative for women struggling with hot flashes. ("Double-blinded" means that neither the study participants nor the researchers knew whether individual participants were receiving the drug or placebo until after the trial ended.)

In addition to evaluating the drug's effect on hot flashes, sleep disruptions, and quality of life, the researchers also looked for potential side effects. Headache and fatigue were the most common, and these were mild. Importantly, there were no [severe side effects](#), which is reassuring for the drug's safety.

"I am excited about the potential of elinzanetant to serve as a nonhormonal treatment option for women with highly bothersome menopausal symptoms who can't or won't take hormone therapy," Pinkerton said. "I hope that it may become a safe and effective non-estrogen option for menopausal women suffering from the triad of moderate to severe VMS, sleep disruption and decreased menopause-related quality of life."

**More information:** JoAnn V. Pinkerton et al, Elinzanetant for the Treatment of Vasomotor Symptoms Associated With Menopause, *JAMA* (2024). [DOI: 10.1001/jama.2024.14618](https://doi.org/10.1001/jama.2024.14618)

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