

Orexin receptor 2 agonist improves sleepiness in narcolepsy

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For patients with narcolepsy type 1, an orexin receptor 2 agonist,

TAK-994, improves measures of sleepiness and cataplexy over eight weeks compared with placebo but is associated with hepatotoxic adverse events, according to a study published in the July 27 issue of the *New England Journal of Medicine*.

Yves Dauvilliers, M.D., from Gui de Chauliac Hospital and the University of Montpellier in France, and colleagues conducted a phase 2 randomized, placebo-controlled trial of TAK-994 in [patients](#) with narcolepsy type 1. Seventy-three patients were randomly assigned to receive twice-daily oral TAK-994 (30 mg [17 patients], 90 mg [20 patients], and 180 mg [19 patients]) or placebo (17 patients).

Owing to hepatotoxic adverse events, the phase 2 trial and extension trial were terminated early. Primary end point data were available for 41 patients. The researchers found that the least-squares mean changes to week 8 in average sleep latency on the Maintenance of Wakefulness Test were 23.9, 27.4, 32.6, and -2.5 minutes in the 30-, 90-, and 180-mg groups and [placebo group](#), respectively. The corresponding least-squares mean changes to week 8 in the Epworth Sleepiness Scale were -12.2, -13.5, -15.1, and -2.1, respectively. The corresponding weekly incidences of cataplexy at week 8 were 0.27, 1.14, 0.88, and 5.83 (rate ratios versus [placebo](#), 0.05, 0.20, and 0.015, respectively).

"The outcomes described in the current report may be seen as a backward step because of the decision to terminate the trial," write the authors of an accompanying editorial. "However, the impressive efficacy is a major step forward in helping patients with [narcolepsy](#) type 1."

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More information: Yves Dauvilliers et al, Oral Orexin Receptor 2 Agonist in Narcolepsy Type 1, *New England Journal of Medicine* (2023). [DOI: 10.1056/NEJMoa2301940](https://doi.org/10.1056/NEJMoa2301940)

Nathaniel S. Marshall et al, Orexin Agonists—Two Steps Forward, One Step Back, *New England Journal of Medicine* (2023). [DOI: 10.1056/NEJMe2305779](https://doi.org/10.1056/NEJMe2305779)

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