

Participating in the DUET Study will help advance research that may better inform how we treat sleep disorders such as IH and narcolepsy. Without participants like you, this important research would not be possible.

Develop hypersomnia
Understanding by
Evaluating low-sodium oxybate
Treatment

Interested in Participating?

To learn more about the DUET Study contact:

Clinical Trial Disclosure and Transparency
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Additional study information is available at
www.clinicaltrials.gov using the identifier NCT05875974.

Effective treatment and reduced sodium intake may work in perfect harmony:

Join the Jazz DUET Study

The DUET Study will evaluate daytime and nighttime effects of XYWAV[®] (low-sodium oxybate oral solution), also known as JZP258, in people with idiopathic hypersomnia (IH) or narcolepsy (Type 1 or Type 2).

References:

1. Sleep and chronic disease. Centers for Disease Control and Prevention. Updated September 13, 2022. Accessed June 1, 2023. https://www.cdc.gov/sleep/about_sleep/chronic_disease.html
2. XYREM and XYWAV. Jazz Pharmaceuticals. Accessed May 25, 2023. <https://www.xywav.com/narcolepsy/lower-sodium-oxybate-treatment-option/>

About the DUET Study

If you're living with IH or narcolepsy, you know that your symptoms can impact how you perform at your job, build relationships and tackle everyday tasks. Activities such as quality time with family and hobbies may be neglected. Even while on treatment, you may still need to continually manage your symptoms.

Lack of quality sleep has been linked to the development of several chronic diseases and conditions, including Type 2 diabetes, cardiovascular disease, obesity and depression.¹ As narcolepsy, and potentially IH, carry a higher risk of developing cardiovascular disease, daily high sodium intake can be a concern. Reducing your sodium intake can help reduce the risk of high blood pressure and heart disease.

The DUET Study will evaluate the daytime and nighttime effects of XYWAV, a low-sodium oral solution for IH and narcolepsy.



Who Can Take Part?

This study is looking for adult participants. To join, you must:

- ✔ Be 18 to 75 years of age
- ✔ Have a primary diagnosis of IH or narcolepsy (Type 1 or Type 2)
- ✔ Have symptoms of excessive daytime sleepiness (EDS) if not currently taking oxybate medication
- ✔ If currently taking oxybate medication, willing to stop for 2 weeks to assess symptoms
- ✔ If currently treated with antiepileptics, alerting agents or nicotine replacement therapy, be on a stable dose with no current plans to adjust the dosage

What is XYWAV?

XYWAV was developed as a low-sodium formulation of XYREM® (sodium oxybate), and it contains 92% less sodium than XYREM.² XYWAV can help reduce sodium intake, a modifiable risk factor for cardiovascular disease. XYWAV is approved for the treatment of IH in adults and for the treatment of cataplexy or EDS in people 7 years of age and older with narcolepsy. The purpose of this study is to evaluate the effects of XYWAV on multiple daytime and nighttime symptoms, as well as functional impacts.

Will All Participants Receive XYWAV?

All study participants will receive XYWAV at no cost during the study. The study doctor will work with you to decide your optimal dosage.

What to Expect

Participation in the DUET Study could last up to 5 months, including a screening period, baseline period, treatment period and follow-up period. Participants are expected to:

- Attend both clinic and virtual visits
 - At the clinic visits, you will complete several questionnaires related to your condition and how you are feeling
 - Some of the clinic visits will be overnight sleep studies
- Take XYWAV orally every night during the treatment period
- Complete daily electronic diaries during the baseline period and treatment period

Enrolling in this study is completely your choice. You may stop participating in the study at any time.

You will be compensated for your travel and time during the study period.

Other Considerations

Prior to enrolling in this study, you cannot have:

- A significant untreated sleep disorder that could impact the study, including sleep-disordered breathing
- A history or presence of a clinically significant medical condition, behavioral or psychiatric disorder
- A schedule that regularly shifts or a job where you work nights
- Plans for travel across more than 3 time zones during the study