



Study Information

A clinical study looking at blood pressure in people with narcolepsy



What is a clinical research study?

A clinical research study is a medical study that helps to answer important questions about a study medication.

The study medication has been approved for use in the United States. Even when a study medication is approved for use, it is not the end of clinical research. It is still important to continue to research the study medication to record any additional benefits and/or side effects.

Choosing to take part in a clinical research study is an important decision. If you have questions, please contact the study team using the information on the back of this brochure.





About the XYLO Study

This is a study looking at blood pressure in people with narcolepsy.

We want to understand more about blood pressure when people with narcolepsy change from a highsodium oxybate medication, like XYREM, to the study medication, XYWAV.

XYWAV has the same active ingredients as XYREM, but with a much lower sodium content.

How can I take part?

To take part, you must be taking or will be taking a high-sodium oxybate.

Some people in this study will participate from home (virtual participants). They will have some home visits with study staff and some telemedicine visits by phone and/or video call. Other people will visit a study center (clinic participants) and will have some telemedicine visits.



Screening

Check if the study is right for you.





Clinic participants: At the study center Virtual participants: Medical staff will come to your home

You will need to:

- wear a blood pressure monitor at home for 25 hours
- collect urine samples at home over 24 hours.

Study treatment

Take the study medication XYWAV nightly, as you do your current medicine.

about 6 weeks



At the end of the study treatment period, you will need to:

- wear a blood pressure monitor at home for 25 hours
- collect urine samples at home over 24 hours.

about 2 weeks

Follow-up

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All participants will have a telemedicine visit to have their health checked.

Study center visit



Telemedicine visit





What will this study involve?

- Taking part for up to 11 weeks, either as a clinic participant or virtual participant
- Having 8 visits with the study doctor or study team in person or by phone and/or video call
- Changing from your current high-sodium oxybate to XYWAV
- Having your blood pressure checked regularly
- Wearing a blood pressure monitor for 25 hours
 - once at the beginning of the study and once at the end
- Making entries into electronic diaries about your sleep and taking your narcolepsy medicine

Who can take part?

We are looking for people who:

- are 18–70 years of age
- have a diagnosis of narcolepsy
- have been taking or will be taking a high-sodium oxybate medication.



What else do I need to consider?

- The study team will explain the possible benefits and risks.
- If you choose to take part, you can stop at any time.
- You may be reimbursed for study visits to cover travel costs or other study-related costs.
- You will receive all study medications and study-related tests at no charge.
- A team of medical staff will monitor your health carefully during the study.





How do I get more information?

Please visit the study website at www.xyloforbp.com or contact the study team using the information provided here.

Study participation is voluntary. You do not have to take part if you contact us.

Additional study information is available at www.clinicaltrials.gov using the identifier NCT05869773.