Narcolepsy & Excessive Daytime Sleepiness (EDS) Study

Study Code: BRP-180-0001

This document provides an overview of a clinical research study evaluating BRP-180, a potential new treatment for Excessive Daytime Sleepiness (EDS) in Narcolepsy and Idiopathic Hypersomnia. It explains the study's purpose, requirements, and what participation involves. Please review this information carefully, and feel free to ask questions or discuss it with your healthcare provider or family.

Why Is This Study Being Conducted?

This study is exploring whether BRP-180 can help improve wakefulness and reduce Excessive Daytime Sleepiness (EDS) in people diagnosed with Narcolepsy Type 1, Narcolepsy Type 2, or Idiopathic Hypersomnia.

Current treatments for EDS may not work for everyone, and this research aims to evaluate the effects of BRP-180 using the Maintenance of Wakefulness Test (MWT), an objective measure of daytime alertness.

Who Can Participate?

You may be eligible if you: ✔️ Are between 18 and 65 years old ✔️ Have a confirmed diagnosis of Narcolepsy (Type 1 or 2) or Idiopathic Hypersomnia ✔️ Experience Excessive Daytime Sleepiness (EDS) ✔️ Meet other specific health criteria assessed during screening

Participation is voluntary, and all eligibility will be confirmed through medical evaluations.

Study Details

- Study Type: Multi-Center, Randomized, Double-Blind, Placebo-Controlled (Phase 2b)
- Sponsor: Bioron Pharma
- Study Locations: Australia
- Total Duration: Approximately 20 weeks per participant

Study Phases:

Screening Phase (Up to 4 Weeks)

Health assessment, medical history review, and baseline tests.

Treatment Phase (8 Weeks)

Participants randomly receive either BRP-180 or placebo.

Regular medical assessments and Maintenance of Wakefulness Test (MWT) evaluations.

Follow-Up Phase (Up to 8 Weeks)

Safety monitoring after completing treatment.

Key Participation Requirements:

- Willingness to complete two MWT assessments to measure wakefulness levels.
- Attend all study-related visits at your assigned clinical site.

What to Expect if You Join?

Regular Health Check-ups

You will have scheduled clinic visits for health monitoring.

Study-Related Tests & Assessments

You will undergo objective sleepiness tests (MWT), symptom tracking, and general health checks.

Potential Benefits

Your participation may help improve understanding and treatment options for people with EDS and related conditions.

Are There Any Risks?

Like any clinical trial, participation in this study comes with some potential risks.

Common Side Effects

Mild nausea, dizziness, headache, dry mouth.

Less Common Side Effects

Changes in blood pressure, heart rate, or mood.

Rare Side Effects

Seizures or significant mood changes (very uncommon).

Your health will be monitored closely throughout the study to ensure your safety.

Privacy & Confidentiality

- ✔️ All personal information will be kept confidential and securely stored.
- ✔️ Your identity will not be included in any study publications or reports.
- ✔️ Only approved study personnel will have access to your data.

Your Rights as a Participant

- Participation is completely voluntary.
- You can withdraw at any time, for any reason, without affecting your usual medical care.
- If you decide to leave the study, you may be asked to complete a final assessment for safety.

Compensation

Participants will receive compensation for their time and travel costs, prorated based on completed study visits. Compensation does not depend on study results and will be explained during screening.

Study Approval & Ethics Oversight

✔️ This study is approved by ethics committees in Australia (HREC) ensuring compliance with ethical research standards.

Contact Information

For Study-Related Questions:

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Ethics Committee Contacts:

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Thank You for Your Interest!

Your participation could make a real difference in advancing treatments for Excessive Daytime Sleepiness and improving the lives of those affected by Narcolepsy and Hypersomnia.