ZEVRA THERAPEUTICS

Do you suffer with symptoms of, or have a diagnosis of idiopathic hypersomnia?

YOU MIGHT QUALIFY TO PARTICIPATE IN THE KP1077.D01 STUDY

WHAT IS IDIOPATHIC HYPERSOMNIA (IH)?

It is a rare, neurological sleep disorder that causes excessive daytime sleepiness. People suffering from IH often live without a correct diagnosis for a long time, blaming themselves and struggling to maintain work, studies and relationships. Common symptoms include:

- Daytime lapses into sleep
- Irrepressible need to sleep that persist even with adequate or prolonged night time sleep (e.g. more than 10–11 hours per night)
- Extreme difficulty waking, despite setting multiple alarms and have difficult rising from bed (known as sleep inertia)
- Experience significantly reduced focus and concentration during waking hours (known as brain fog)

Learn more about IH and the challenges of diagnosis at ***www.hypersomniafoundation.org***

WHAT IS STUDY KP1077.D01?

Study KP1077.D01 is a clinical trial evaluating the safety and efficacy of KP1077 capsules in adults with idiopathic hypersomnia (IH).

KP1077 capsules contain serdexmethylphenidate (SDX), a prodrug which becomes modified to its active form of dexmethylphenidate (d-MPH) in the digestive tract after ingestion. SDX is an investigational medication for treating excessive daytime sleepiness (EDS) and other symptoms of IH. SDX has a unique, slow release profile that could potentially provide stable control of sleepiness throughout the day, with low abuse potential.

HOW TO FIND A CLINICAL SITE PARTICIPATING IN THE STUDY?

There are over 40 study sites in the US currently recruiting. There are several ways to find a participating site:

1. See the list of locations and contact information attached or visit ***www.KP1077D01.com***
2. Check out ***NCT05668754*** on clinicaltrials.gov for participating sites
3. Email ***medicalaffairs@zevra.com***

WHAT IS THE PURPOSE OF THE STUDY?

In this study, researchers will evaluate the safety of the medication and its effect on symptoms and severity of IH, including the effect on EDS, sleep inertia (difficulty of waking up in the morning), and brain fog (lack of focus and mental clarity; forgetfulness and confusion).

WHAT ARE MY COSTS TO TAKE PART IN THIS STUDY?

Participants do not have to pay for the study drug, study supplies, examinations or tests that are part of the study. Participants who have not previously been diagnosed with IH and need to be diagnosed in a sleep clinic, will not have to pay for this procedure. Participants will be reimbursed for expenses incurred during trial, including coverage of travel costs to the clinical sites for all their clinic visits that are part of the clinical trial. Participants can talk to the staff of their clinical site to facilitate travel arrangements and expense related reimbursements.

WHO IS ELIGIBLE TO PARTICIPATE IN THE STUDY?

Adults (18 years of age or older) who meet the following criteria may be eligible to participate:

- Diagnosed with IH
- Have symptoms of IH but not yet diagnosed by their doctor may also be eligible; their diagnosis will be checked in the screening period of the trial
- Have excessive daytime sleepiness as measured by sleepiness questionnaires
- Able to give informed consent
- Agree to wash out all current medications that may affect daytime sleepiness or nighttime sleep
- Are not pregnant, or do not plan to get pregnant or breastfeed during the study

This is not a complete list of eligibility criteria. The study doctor will review all requirements with you.

WHAT CAN PARTICIPANTS EXPECT OF THIS STUDY?

Participants will visit their study site at regular times over a period of up to 12 weeks spanning approximately 10 visits (most of which are 1 week apart) for exams and tests by the study doctor, and to receive their supply of study drug. Between study visits, participants will take study drug daily at home and fill in questionnaires about how they feel about their condition.

This clinical study consists of the following study periods:

- A screening period (up to 5 weeks) during which eligibility criteria will be evaluated including a confirmation of participant's IH diagnosis, if needed
- A 5-week dose optimization period in which all eligible study participants will receive study drug orally once or twice per day. Participants will be assigned into two evenly divided groups. One group will receive a single daily dose just before bedtime, and the other group will receive half the daily dose shortly after awakening and half the daily dose just before bedtime
- A 2-week double-blind randomized withdrawal period wherein participants receive their optimized dose daily or a matching placebo. "Double-blind" means that study participants and doctors won't know who is receiving active study drug or placebo. "Placebo" is a capsule that looks the same as the active study drug capsule but does not contain active study drug. "Randomized" means that the assignment to active study drug or placebo is random (determined by chance)

For additional details about the study, visit ***NCT05668754*** on clinicaltrials.gov.

ABOUT CLINICAL STUDIES

What is a clinical study?

In a clinical study (also called clinical trial), participants are assigned to one or more study drugs to learn more about the study drug, to find out if it works (efficacy) and to help researchers learn more about its potential side effects (safety).

Why are clinical studies so important?

Clinical studies are important for medical advances. Current treatments for diseases are only available because of the volunteers who participate in the clinical studies. This clinical study is being conducted by a pharmaceutical company as part of its research to learn more about an investigational drug in adults with IH. Study volunteers can help in this important research.

What is a study drug?

A study drug is a substance that is being tested in clinical studies. It is also called an investigational drug. An ethics committee has reviewed the clinical study for testing in people.

What is a prodrug?

A prodrug is an inactive compound that needs to be metabolized in the body to produce an active drug. Serdexmethylphenidate (SDX) is a prodrug of dexmethylphenidate (d-MPH). After oral ingestion, SDX is converted to d-MPH, likely in the lower gastrointestinal tract. d-MPH belongs to a group of medications called central nervous system (CNS) stimulants or psychostimulants, with the capacity to simulate the CNS.

Thank you for considering participating in this study!