Do you have idiopathic hypersomnia?

You might qualify to participate in the KP1077.D01 study

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 of dexmethylphenidate. It 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.

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).

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. Patients with 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.
- Able to give informed consent.
- Have excessive daytime sleepiness as measured by sleepiness questionnaires.
- 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 the 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 patient'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 patients 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.

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. Patients who have not previously been diagnosed for IH and need to be diagnosed in a sleep clinic, will not have to pay for this procedure. Patients will be reimbursed for their participation, 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 reimbursements.

How to find a clinical site participating in the study?

There are several ways to find a participating site:

1) Check out NCT05668754 on clinicaltrials.gov for participating sites
2) Email medicalaffairs@kempharm.com
3) Call 1-888-289-5607 and leave a message.

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!