What is a clinical study?

In a clinical study, participants are assigned to one or more study drugs to learn more about the study drug, to find out if it works or works better than other treatments, and to find out if it has side effects.

What is a study drug?

A study drug is a substance that is being tested in clinical studies. It is sometimes called an investigational drug. An ethics committee has reviewed the clinical study for testing in people and the study drug may or may not be approved by the government health agency for treatment for the condition being studied.

Why should I take part in this study?

Clinical studies (also called clinical trials) are important for medical advances. Current treatments for diseases are only available because of clinical study volunteers.

Thank you for your interest in this study for idiopathic hypersomnia.

For more information, please visit **www.intuneihstudy.com** or contact:

HARMONY BIOSCIENCES | INTUNE

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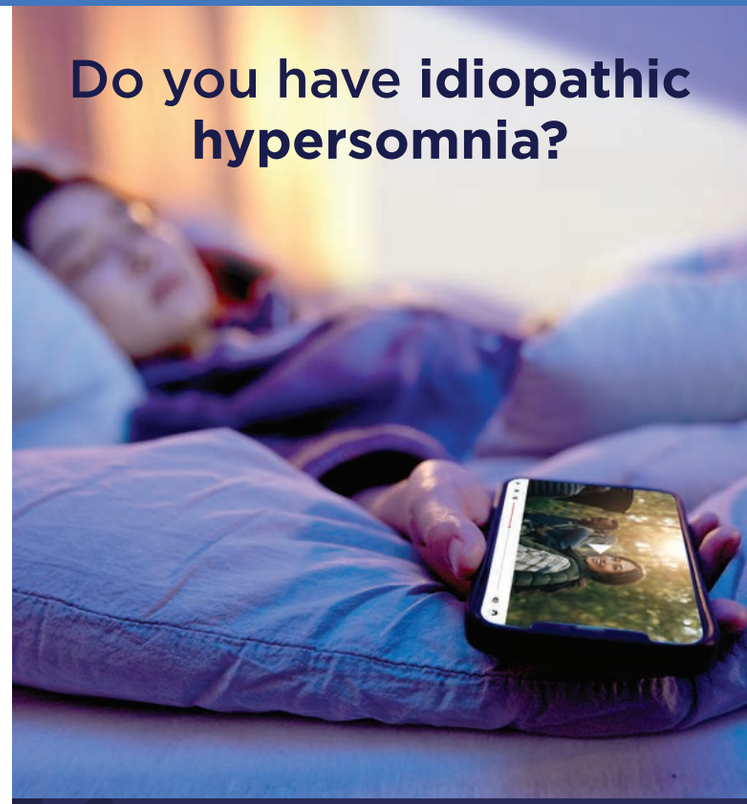
Do you have idiopathic hypersomnia?



Consider the INTUNE study.

Ask your doctor if you are eligible for this study.

INTUNE

Why is this study important?

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 idiopathic hypersomnia (IH). Study volunteers can help in this important research. Thank you for considering participation in this study.

What is the purpose of this study?

In the INTUNE study, researchers will evaluate the safety and efficacy of an investigational study drug, pitolisant, for excessive daytime sleepiness and other symptoms in adults with IH.

Who can participate in this study?

To be eligible for this study, you must be:

- 18 years of age or older
- Diagnosed with idiopathic hypersomnia
- Able to give informed consent

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

What can I expect if I decide to participate?

After a 28-day screening period, all eligible participants will receive daily doses of the study drug, pitolisant, for 8 weeks. After the 8-week period, study staff will evaluate participants to confirm eligibility to participate in the 4-week double-blind randomized withdrawal phase. During this phase, study participants will either receive daily doses of the study drug or placebo. A placebo is a tablet that looks like the study drug but has no study drug in it. Neither the study participant nor the study doctor will know if the participant is receiving the study drug or a placebo.

Screening Period	**Open-Label Phase**	**Randomized Withdrawal Phase**
28 days	*8 weeks*	*4 weeks*

Participants will be in the study for up to approximately 4-5 months and will need to come to the study center 5 times. There will also be 7 telephone calls that will take place during the study.

After the final study visit, participants will have the opportunity to participate in an additional long-term safety study. If a participant chooses not to participate in the long-term safety study, they will have 2 safety follow-up telephone contacts approximately 15 days and 30 days after the last dose of study drug.

Lab tests, physical exams, other assessments and questionnaires will be conducted as part of the study.

What are my costs to take part in this study?

You do not have to pay for the study drug, study supplies, or tests that are part of the clinical study.

What risks are involved if I decide to participate?

There are possible risks involved with any clinical study. Your study doctor will review the risks with you, and you will be closely monitored throughout the study.