Sleep disorders, such as narcolepsy with cataplexy, present daily challenges and frustrations. Individuals may struggle with activities that others take for granted, such as working, driving, and watching television. Even spending time with family and friends can be difficult when it is a constant fight to stay awake.

Further development is needed in treating narcolepsy with cataplexy.

About Clinical Studies

Clinical studies are how prevention and treatment options for diseases and health conditions are developed. These studies provide valuable information about safety and effectiveness before an investigational drug or treatment is approved.

Clinical research studies follow standards and are closely regulated. Strict safety measures protect study participants, and a written plan called a protocol ensures that all study procedures are conducted in accordance with standards and regulations.

To learn more or to see if you may qualify for the SPARKLE 1501 study, visit

MyNarcolepsyStudy.com

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SPARKLE 1501
NARCOLEPSY WITH CATAPLEXY

The SPARKLE 1501 Study Overview

If you have narcolepsy with cataplexy, you may be able to help with research to develop a new treatment option.

MyNarcolepsyStudy.com

What is the SPARKLE 1501 Study?

The SPARKLE 1501 Study is testing an investigational drug in people with narcolepsy with cataplexy. The main purpose of the study is to look at how safe and tolerable the investigational drug is and how it may affect your narcolepsy symptoms.

Who can participate in this study?

You may qualify to participate if you:

- Are 18–65 years old
- Have been diagnosed with narcolepsy with cataplexy (also known as narcolepsy type 1)
- Are willing to stop taking narcolepsy medications during study participation
- Meet additional requirements as determined by a screening process

What drug is being tested?

The investigational drug is called TAK-994. It is designed to turn on the orexin system in the brain. The orexin system plays a part in regulating wakefulness (keeping people awake).

Will I receive the investigational drug?

Two-thirds (about 67%) of study participants will receive the investigational drug. The other third (about 33%) will receive a placebo. You will be assigned one of these two study treatments by chance. Neither you nor the study doctor or staff will know which study treatment you receive.

What is a placebo? Why is it used?

A placebo looks like the investigational drug but contains no active ingredients. Placebos are often used in clinical research studies to help evaluate the investigational drug by comparing effects seen in study participants who take the investigational drug to effects seen in those who take the placebo.

What will happen at the clinic?

You will talk with the study doctor or staff about how you are feeling. The study doctor or staff will also perform scheduled assessments and procedures to monitor your health and potential effects of your study treatment.

Can I leave the study after I start?

You can stop taking part in this study at any time. If you choose not to take part or you agree to take part but then withdraw, medical care you receive outside the study will not be affected. The study doctor will discuss other treatment options with you.

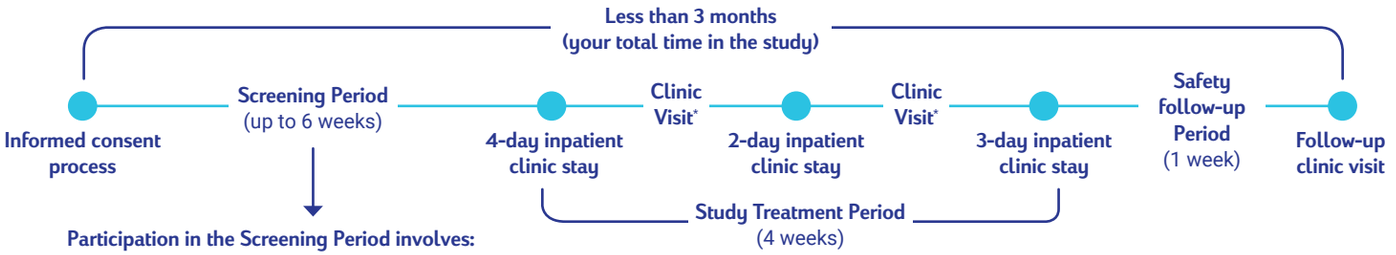
Will I need to make any lifestyle changes?

During the study, you will need to avoid:

- All narcolepsy medications, as well as some additional medications and supplements
- Certain foods and beverages
- Strenuous activities

The study doctor will discuss study restrictions with you during the informed consent process.

- **Your participation will last less than 3 months**
- **Travel support may be available**
- **You may be compensated for your participation**



Participation in the Screening Period involves:

- Undergoing assessments at a screening visit to determine if you qualify to participate in the study
- Recording information in an electronic diary about your sleeping and cataplexy
- Stopping your medications for narcolepsy with cataplexy at least 7 days before checking in for your first multi-day inpatient clinic stay

Participation in the Study Treatment Period involves:

- Taking your study drug (TAK-994 or placebo, as assigned by chance) twice daily, as directed
- Recording information in an electronic diary about your sleeping and cataplexy
- Attending 3 multi-day inpatient clinic stays and 2 additional clinic visits*

**You may have the option to stay at the inpatient clinic the night before visits that require morning check-in.*