

What will happen at the study visits?

The study team will provide all study-related health tests and assessments. You will have to follow a few instructions and have some tests and assessments. They will include:

- questions about yourself, your health history, and any medications you are taking
- physical exam and vital signs, such as blood pressure and breathing rate
- electrocardiogram (ECG), to make sure your heart is healthy
- an alcohol breath test, to check if you have consumed alcohol recently
- urine and blood samples, to check your health
- a wakefulness test, to check for your ability to stay awake
- taking your study medication capsule by mouth with water
- restricting smoking on study visit days
- questionnaires to complete
- pregnancy tests (for women who are able to become pregnant).

What else do I need to know?

- Your participation in this study is entirely voluntary. If you decide to take part, you can leave the study at any time without giving a reason.
- If this study is right for you, all study-related medications, examinations, and medical care will be provided at no cost to you.
- Taking part in a clinical research study involves some risks, but may also provide benefits. The potential risks and benefits of this study will be explained in detail by the study team.
- You will be asked to sign an Information Sheet and Consent Form before taking part in this study.
- Taking part in this study may or may not directly benefit you. However, the information gathered from this study will help to improve our knowledge of the investigational medication, and may benefit people with PD-related sleepiness in the future.
- You will still see your regular doctor, who will continue to be responsible for your care.

How do I find out more?

To learn more about the PASSAGE Study, please contact the study team today.

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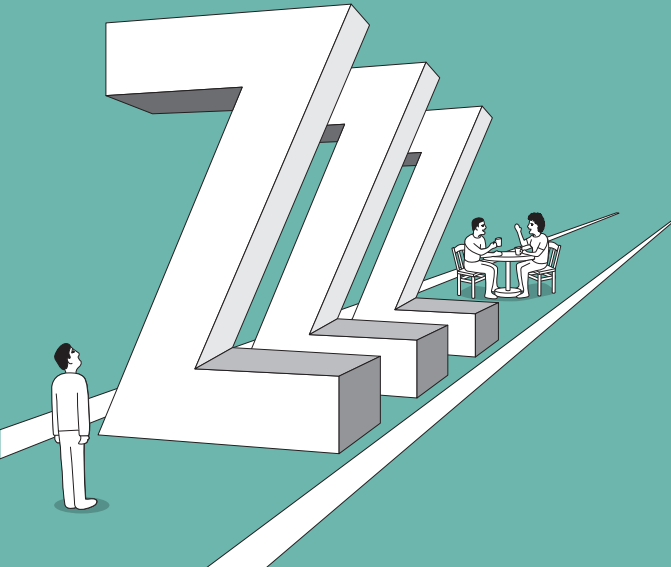
Thank you for considering taking part in the PASSAGE Study.



PASSAGE
PARKINSON'S DISEASE
STUDY IN PATIENTS WITH
EXCESSIVE SLEEPINESS

Parkinson's Disease Research
and an Excessive Daytime
Sleepiness Treatment Option

STUDY
INFORMATION



What is the PASSAGE Study?

The PASSAGE Study is a clinical research study looking at the safety and efficacy of an investigational medication for sleepiness in patients with Parkinson’s disease (PD). A clinical research study is a medical study designed to answer important questions about a potential new medication (called an investigational medication), such as whether it improves a patient’s health or causes any side effects.

The PASSAGE Study will:

- look at an investigational medication that comes as a capsule taken with or without food, once a day with water in the morning, after waking up
- look at how the investigational medication affects your level of sleepiness, how it works in your body, and how safe it is
- last for about 9 weeks and involve 7 visits to the study center
- enroll a total of 49 people in 15 study sites in the United States



- look at whether the investigational medication reduces sleepiness in patients with PD, by comparing the response with a placebo (which looks like a medication but contains no active ingredients)
- test which dose of the investigational medication works best to reduce sleepiness
- let you continue taking your regular PD and certain sleep medications during the study
- place you into 1 of 3 groups using a computer that assigns you by chance, like drawing names from a hat. Most people (42 of 49) in the study will receive the investigational medication. The rest of the people (7 of 49) will receive the placebo only. Both you and the study doctor will not know which medication you are receiving.

Why is the PASSAGE Study needed?

As you may have experienced, PD can involve different types of symptoms. Some are motor (movement) symptoms, like a tremor (uncontrollable shaking), and some are non-motor symptoms such as a loss of smell, mood changes, and/or sleep problems.

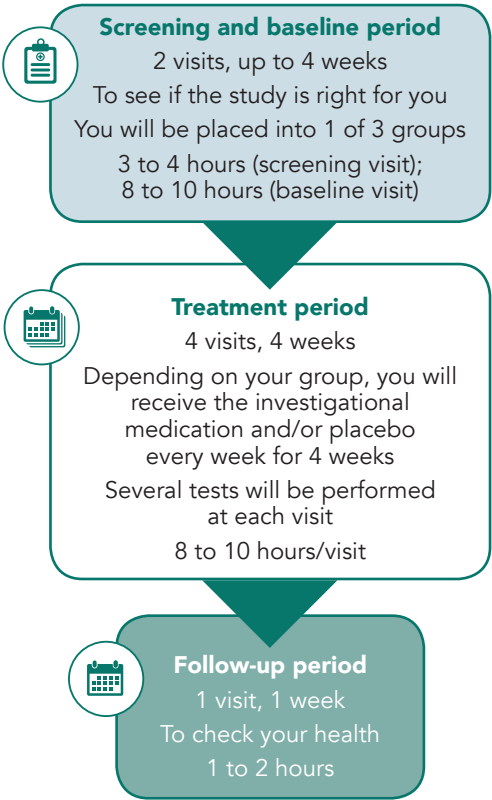
Sleepiness during the day and waking up at night can affect you and the people around you. The PASSAGE Study is looking at a potential new medication for excessive sleepiness in people with PD.

Who can take part in the PASSAGE Study?

You can take part in the study if you:

- are between 35 and 80 years of age (inclusive)
- have a diagnosis of PD
- experience excessive daytime sleepiness, despite spending 6 or more hours in bed
- have not been diagnosed with obstructive sleep apnea or narcolepsy.

What will taking part in the PASSAGE Study involve?



As these visits are long, you may have to arrange to cover your responsibilities at work and/or home.

- You may continue taking your PD and certain sleep medications as usual during the study, but will need to tell the study doctor about any medications you are taking or plan to take – even those you can buy over the counter at a store. Some medications may not be allowed.
- Your health will be monitored carefully throughout the study, and you will receive the treatment you need if you feel unwell. You will be asked to call the study team using the contact information in this brochure if you experience any problems or changes in your health.
- You may be compensated for your time in the study.



We understand the PASSAGE Study involves a big time commitment, and we want to make sure you agree to full participation from the start.