What is informed consent?

Before you take part in this study, you will read and sign an informed consent form (ICF). This form will tell you what will happen during the study. You can ask as many questions as you want before you sign this form. Taking part in the study is voluntary, and you may leave the study at any time.

What medical tests will I have during the study?

Tests and assessments during the study include:

- Talking about your medical history and medications you have taken
- Physical exams
- Questionnaires about your sleep and mood
- Neurological exams
- Vital signs (heart rate, temperature, respiratory rate, and blood pressure)
- Height and weight
- ECGs (electrocardiograms, a heart test)
- Blood and urine tests
- Drug screen and alcohol breathalyzer tests
- Urine pregnancy test (if applicable)
- Talk about any side effects you may experience
- Wakefulness tests to see how well you resist falling asleep
- Polysomnography (overnight sleep monitoring)

How do I learn more?

To learn more about this study, including the possible risks and benefits of taking part, please contact:

Delta Waves Inc.

Research@Deltawaves.org

(719) 262-9283

www.deltawaves.org

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MK6552-004_Recruitment Brochure_V1_06NOV2023

MK6552-004 CLINICAL RESEARCH STUDY

LEARN ABOUT A CLINICAL TRIAL FOR ADULTS WITH NARCOLEPSY

MERCK

What are clinical studies?

Clinical trials are research studies that help doctors find out if study drugs (alone or with other treatments) are safe and if they can help prevent, find, or treat diseases or conditions. Clinical trials are carefully controlled research studies that are done to get a closer look at investigational treatments and procedures.

What is the purpose of this study?

This study is testing an investigational study medication for narcolepsy, a sleep disorder that causes daytime sleepiness. Researchers want to learn if the investigational study medication is safe, how well it works, and how your body responds to the investigational study medication compared to a placebo. A placebo looks like the investigational study medication but has no active ingredients.

Can I take part in this study?

You may be able to take part in this study if you are 18-55 years old and:

- Have been diagnosed with narcolepsy for at least 6 months
- Sleep more than 6 hours at least 4 out of 7 nights in a week
- Usually fall asleep by midnight
- Are able to stay overnight at the study clinic at least 2 nights in a row on 8 different occasions throughout the study

There are other requirements to be in the study. The study staff will do tests and also discuss all the requirements to join this trial and decide if you qualify.

What is the investigational study medication?

The investigational study medication is a capsule taken by mouth.

Will I get the investigational study medication if I take part?

The study is divided into 2 parts. In Part 1, all participants get the investigational study medication in increasing doses. In Part 2, participants will get the investigational study medication for 7 days and the placebo for 7 days in a random order. The dose of the investigational study medicine will depend on the safety and tolerability observed in part 1 of the study. The placebo looks like the investigational study medication, but it does not contain any active ingredients.

What will happen if I take part?

If you qualify and decide to take part, you will be in the study for about 11 weeks (about 2 and a half months). This study has different parts:

- ***Screening (up to 4 weeks long):***
  You will have medical tests to see if you qualify. You will visit the study site at least once and receive phone calls from a member of the study staff.
- ***Intervention (about 5 weeks long):***
  This is divided into 2 parts.
  - During Part 1, you will get the investigational study medication. This part includes 4 overnight stays, which will last at least 2 nights for each stay at the study clinic.
  - During Part 2, you will get the investigational study medication and a placebo. You will stay overnight at least 2 nights at the study clinic 4 times. While at home, you will continue to take the investigational study medication or placebo. You will record this in the medication diary, which will be provided to you by the study staff. Study staff will briefly check in with you on a daily basis by phone.
- ***Follow-up (2 weeks long):***
  About 2 weeks after you take the last dose of the investigational study medication or placebo, you will have a clinic visit. You may also receive a phone call from the study doctor or a member of the study team a few days after the clinic visit to ask how you are doing.