We understand how important it is for those who suffer from depression to find an effective treatment. Different types of oral antidepressants work in different ways. For reasons that medical scientists do not fully understand, the degree of symptom relief from various oral antidepressants can differ from patient-to-patient. Many patients find that while they get some symptom relief from the antidepressants they have tried, the relief is simply not adequate for them.

The SOLEO study will enroll participants suffering from major depressive disorder and is designed to assess the efficacy of the study drug for people who have tried other treatments for major depressive disorder without sufficient improvement.

In this research study, we are evaluating a drug called CLE-100. It is a tablet taken once daily in addition to current oral antidepressant. The study drug is an investigational therapy, which means it is still being tested in clinical research studies. It has not been approved by the US Food and Drug Administration (FDA) or other Health Authorities to be prescribed for treatment. If you decide to join the SOLEO study, you will be randomly assigned (like the flip of a coin) to receive either the study drug or placebo (no active ingredients) for 4 weeks after which participants will be offered the opportunity to receive the active study drug for a period of 6 months.

soleo study

FOR MORE INFORMATION ABOUT THIS RESEARCH STUDY, PLEASE CONTACT:

Psych Atlanta - Research
Phone: 770-422-2846
Email: research@psychatlanta.com

Version: 24May2024-v1

Still feeling SYMPTOMS OF DEPRESSION despite taking prescription medication?

If so, participating in our medical research study may be an option for you.

Learn more >>

soleo study

Study Overview

Below is a description of the different parts of this study.

Consent

Before a potential participant can proceed with this study, the study staff will review with them the informed consent form to provide a detailed explanation of this study and its potential risks and benefits. After this explanation, the study staff will answer any questions. Then, if the potential participant wishes to proceed, they will sign the informed consent form to confirm that they understand and are willing to participate in the study. Study participation is completely voluntary at all times.

Screening

After consent has been given, the screening period of the study will begin. During screening, the study staff will review medical history and conduct a series of study-related examinations, questionnaires, and laboratory tests to see if the study requirements are met. The screening period will last up to 28 days.

Double-Blind Treatment Period

Participants who satisfy the study requirements and wish to proceed with the study will be assigned to take either CLE-100 or a placebo. In this brochure, whichever is assigned, CLE-100 or placebo, will be called the "study drug." Neither the study participant nor study staff will know which study drug has been assigned. This is why this Treatment Period is called the Double-Blind Period.

The assigned study drug will be taken once per day. Participants will continue taking their already prescribed oral antidepressant. Participants will not be allowed to drive within 8 hours of taking the study drug. Sometimes the assigned study drug will be taken at the study clinic and most of the time at home. When taken at home, the study drug will be taken at bedtime. A car service will take participants to and from the study clinic.

Optional Extension

Participants who complete the Double-Blind treatment period may be offered the option of receiving active study drug for a six-month period at no cost.

Participation Requirements

To join this study, potential study participants:

- must be 18 to 65 years of age
- must be experiencing a depressive episode that began at least 12 weeks before the screening visit
- during the current episode, must have tried at least 2 (but no more than 5) antidepressants that did not provide adequate symptom relief

This is not a complete list of study requirements. The staff at the study clinic will explain the complete list of requirements.

Costs and Expenses

There is no cost to participate. There will be compensation provided for completed visits for participant's time and effort. Transportation will be included to and from the study site.

Risks and Benefits

All drugs and medical procedures carry a risk of side effects. Therefore, it is possible that participants may experience some discomfort or other reactions from the use of CLE-100 or from the study procedures or tests. The study staff will explain these risks before potential participants decide whether to participate in the study. The safety of participants will be closely monitored throughout the study.

Participants will help contribute to the testing of CLE-100 and the information learned from this study may help find treatment options in the future for people who suffer from depression. There is no guarantee that study participants will receive any direct benefit from their participation.

Next Steps

If you are interested to learn more about this study, please contact us using the information on the back of this brochure. If you contact us, you will not be obligated to participate in this study. Participation is entirely voluntary. Should you qualify for participation and decide to participate in the study, you may stop your participation at any time with no adverse impact to the care you receive outside of the study.