What is the uASPIRE Study?

The purpose of this clinical research study is to determine the safety and effectiveness of treatment with psilocybin in adults diagnosed with major depressive disorder (MDD). Currently available treatments for depression may not work for everyone, so alternative treatments are being sought through clinical research studies.

The uASPIRE Study is testing a single oral dose of an investigational drug for the treatment of MDD. We will look at the investigational drug to learn how well it relieves the symptoms of a major depressive episode compared to treatment versus a placebo group. Participants will also receive psychosocial support—sessions that address a person's emotional, social, mental, and spiritual needs—throughout the study from trained study facilitators.

What is major depressive disorder?

MDD is a mood disorder that causes a persistent feeling of sadness and loss of interest. It affects how you feel, think, and behave—and can lead to a variety of emotional and physical problems. It is often diagnosed when someone has a persistently low or depressed mood, feelings of guilt or worthlessness, lack of energy, sleep disturbances, and suicidal thoughts. For many people with MDD, symptoms are often severe enough to impact daily activities, such as work, school, relationships, and social activities.

What is the investigational drug?

The investigational drug, psilocybin, is a naturally occurring psychedelic compound produced by more than 200 species of fungi. In previous studies, psychedelics like psilocybin have shown promise in their ability to alleviate symptoms of depression and provide an increased sense of well-being in some participants.

What is a clinical research study?

A clinical research study is designed to test an investigational drug to determine if it works and is safe. This study will help researchers learn more about the safety and effectiveness of the investigational drug, potentially providing a new treatment option in the future for people with major depressive disorder.

Participation in this clinical research study is completely voluntary. Your decision to participate or not participate will have no effect on the medical care you receive now or in the future. If you are eligible to participate in the uASPIRE Study and choose to participate, you may stop participating at any time and for any reason.

Learn more about the uASPIRE Study

Please speak with your treating physician or a member of the study team if you have questions about the uAspire Study.

CONTACT UNM STUDY TEAM TO LEARN MORE AND FIND OUT IF YOU ARE ELIGIBLE:

Text or leave message at
(505) 600-1448
or email uASPIRE@salud.unm.edu
HRRC #24-167

uAspire

PSIL301 – PFM – Recruitment Brochure – US/ENG – V1.0– 02MAY2024

Have you been diagnosed with major depressive disorder (MDD)?

Explore Alternative Approaches to Treatment for MDD

uAspire

Study design

You will be randomly assigned to one of three groups:

- A dose of the investigational drug at 25 mg.
- A lower dose of the investigational drug at 5 mg.
- A placebo dose that does not contain any active investigational drug.

You'll receive a single dose of the investigational drug (or placebo) at the start of the clinical trial. However, if your depression relapses during the Long-Term Follow-Up Period, you may be eligible for up to four additional doses of the investigational drug—at a dose of 25 mg—regardless of your initial study treatment group.

The image(s) depicted contain models and are being used for illustrative purposes only.

What happens in the study?

You'll be in the study for up to 64 weeks. The study includes the following periods:

Screening Period (Up to 5 Weeks):

- You'll sign the Informed Consent Form (ICF), which explains your responsibilities throughout the study, and have some tests done to see if you are able to join. If you are eligible and choose to join, you'll begin tapering off your current medications. These tests may happen over more than one visit.

Preparation and Dosing Period (Up to 1 Week):

- You'll have a Preparation Session before your Dose Visit, where you'll talk with the study doctor about what to expect at your dosing appointment.
- On your dosing day, you'll be randomly assigned to one of three dosing groups. You'll then receive either the investigational drug or placebo (you won't know which you receive) and discuss your experience during a post-dose Integration Session.

Double-Blind Period (Up to 6 Weeks):

- You'll complete two additional Integration Sessions after dosing and have several visits where you'll complete assessments and be monitored for any adverse effects.

Long-Term Follow-Up Period (Up to 52 Weeks):

- At the conclusion of the Double-Blind Period, you'll enter the 1-year Follow-Up Period.
- During the Follow-Up Period, you'll have a telephone check-in every 2 weeks and clinic visits every 3 months starting 12 weeks after beginning the Follow-Up Period.
- You'll attend Remote Peer Support and Psychoeducation Group Sessions twice a month for 3 months and then once a month for the next 9 months.
- If you're eligible for further doses of the investigational drug, you'll have a Preparation Session and Integration Sessions for each additional dose.

Who is eligible for the study?

You may be eligible if:

- You are at least 18 years old.
- You have been diagnosed with major depressive disorder (MDD).
- You have been experiencing a major depressive episode for at least 60 days.
- You are willing to stop taking medication for your condition until the end of the study and not start new types of therapy during the study.

There are other requirements to be eligible for this study. The study team will discuss them with you and give you an Informed Consent Form (ICF) to sign if you would like to participate in the uASPIRE Study.

Are there any costs for study participation?

If you are eligible and choose to participate in the study, you will receive the following at no cost:

- The investigational drug and other study treatments.
- Any study-required visits, tests, and assessments.

Only the study doctor can confirm your eligibility. To see if you may be eligible, please speak with a member of our study team to schedule a Screening Visit.