A Phase III, multicentre, randomised, double-blind, placebo-controlled study to investigate the efficacy, safety, and tolerability of COMP360 in participants with treatment-resistant depression

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: 18 years and over
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- diagnosis of major depression without psychotic features - if the current major depressive episode is the first episode of depression, the length of the current episode must be at least 3 months and no more than 2 years - have not responded to an adequate dose and duration of two, three, or four different medications to treat the current episode - agree to discontinue all prohibited medications (study staff will review)

Exclusion Criteria:

- any additional major mental health diagnosis - required psychiatric inpatient care in the past 12 months - treatment with electroconvulsive therapy, deep brain stimulation, or vagus nerve stimulation during the current depressive episode - transcranial magnetic stimulation within the past six months - in a psychological therapy program that will not remain stable for the duration of the study

Conditions & Interventions

Interventions:
Drug: Psilocybin
Conditions:
Mental Health & Addiction
Keywords:
TRD, Treatment Resistant Depression

More Information

Description: COMP360 is a human-made form of the naturally occurring chemical compound, psilocybin which may help in treating depression. In this research study we are comparing COMP360 to placebo, when administered with psychological support from a trained study therapist. Placebo is a substance that has no active medical ingredients and is commonly used in research studies to see if the investigational drug works better or is as safe as not taking anything at all.
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